

INFUSO.R.TM Pump

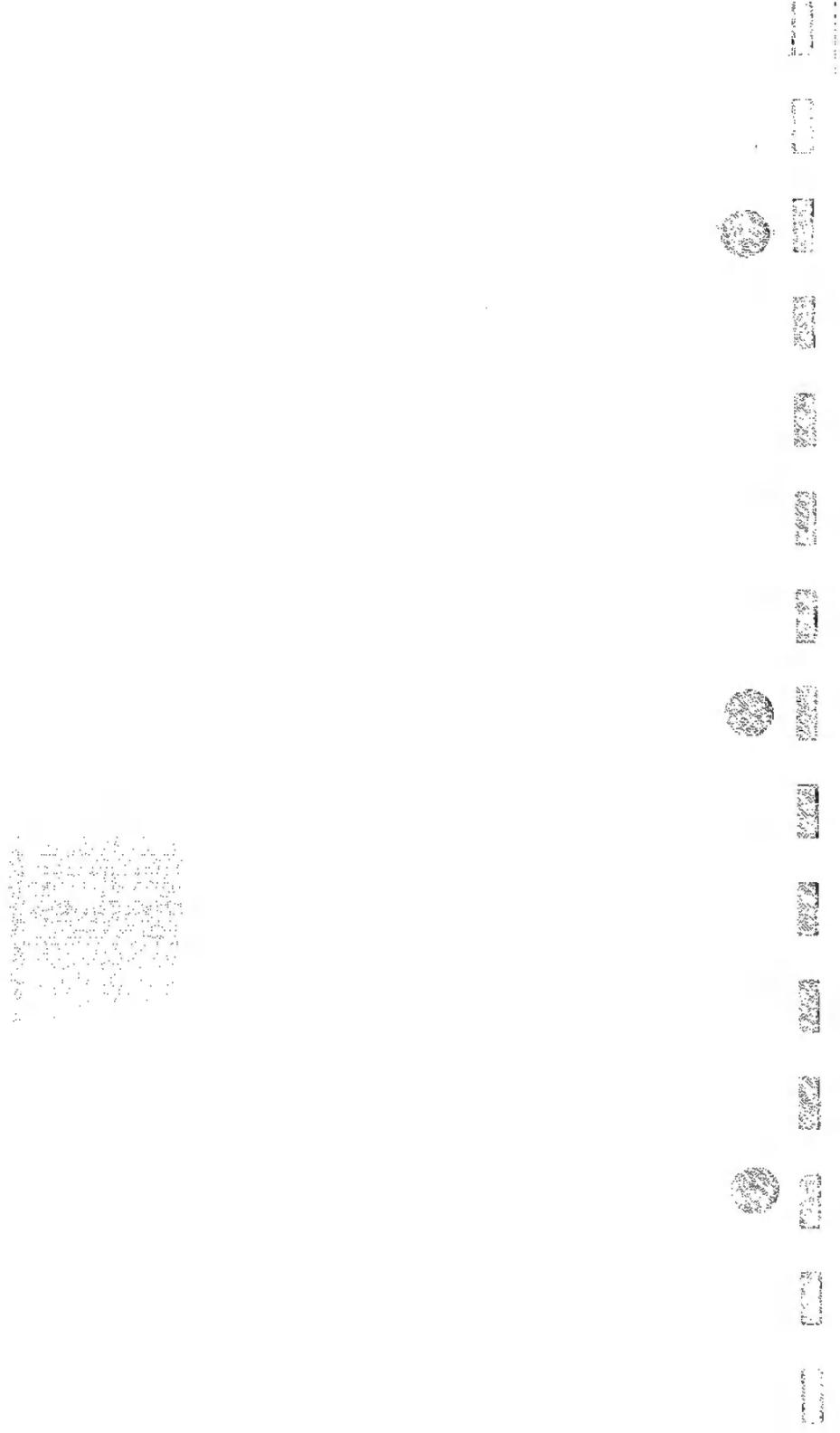
User's Manual

Baxter

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

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***INFUSO.R.™ Pump* USER'S MANUAL**

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Issue Date: December 1998

**WARNING: AN ISSUE DATE FOR THESE
INSTRUCTIONS IS INCLUDED
FOR THE USER'S INFORMATION.
IN THE EVENT TWO YEARS HAVE
ELAPSED BETWEEN THIS DATE
AND PRODUCT USE, THE USER
SHOULD CONTACT BAXTER
HEALTHCARE TO SEE IF
ADDITIONAL PRODUCT
INFORMATION IS AVAILABLE.**

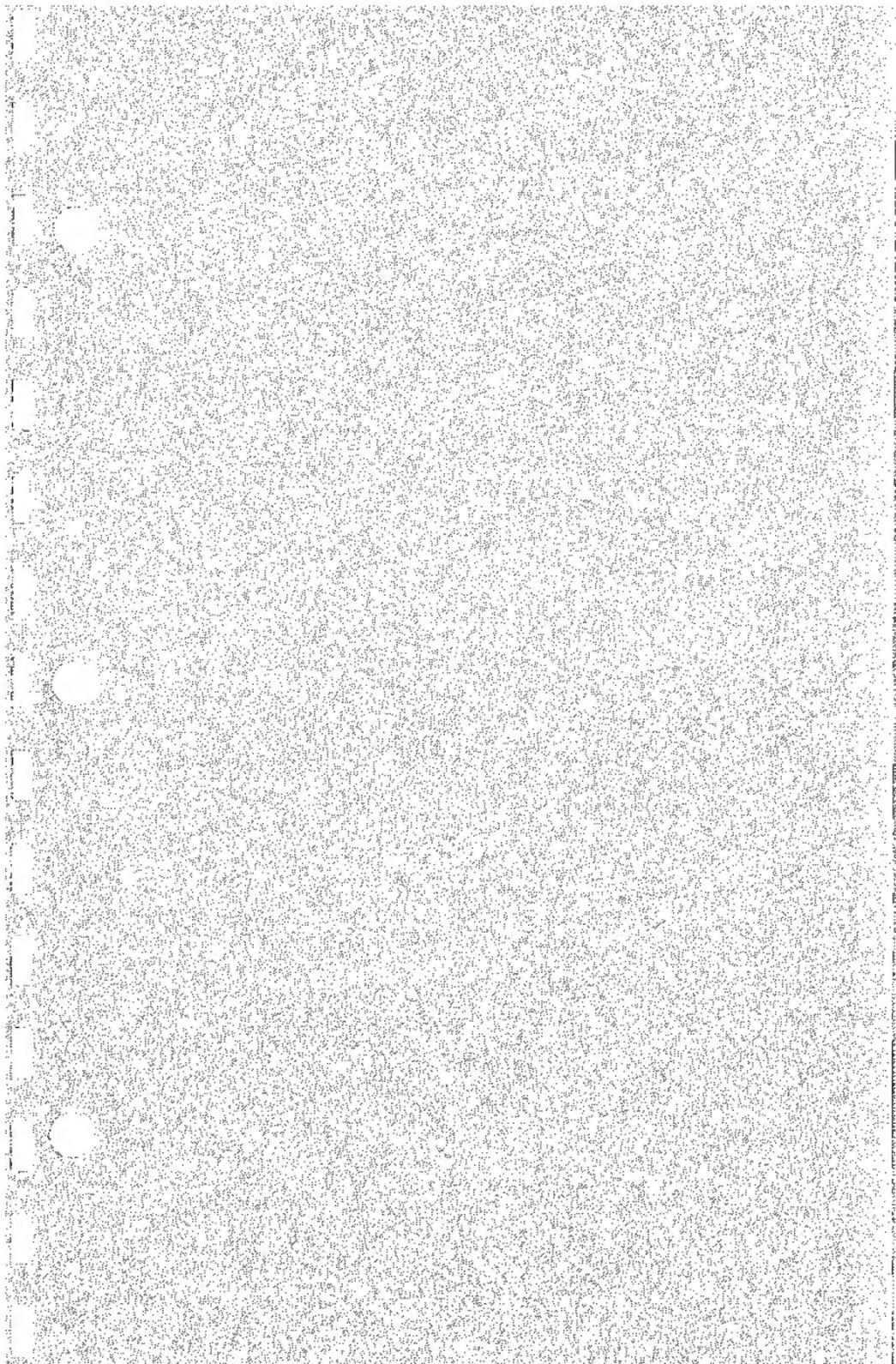
**Caution: Federal (USA) law restricts this device to sale
by or on the order of a physician.**

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***INFUSO.R.* is a trademark of Baxter Healthcare
Corporation.**

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I. General Introduction

The **INFUSO.R.** Pump is a syringe infusion device that will aid in the administration of many intravenous agents given during anesthetic procedures. In conjunction with the Smart Label System, it provides for the convenient delivery of narcotics, muscle relaxants, vasoactives and other drugs routinely given during anesthesia. The Smart Label System is a set of drug specific labels that attach to the front of the **INFUSO.R.** Pump. Each Smart Label converts the **INFUSO.R.** Pump into a specific delivery system for the indicated drug with appropriate rate selections and delivery units. By simply changing the specially coded Smart Label, the **INFUSO.R.** Pump is automatically changed to a specific delivery system for a particular intravenous agent.

The **INFUSO.R.** Pump is easy to set up and use. Each Smart Label is clearly marked with drug dilution instructions and the required syringe size. The pump accepts B-D® or Monoject® 20 cc and 60 cc plastic disposable syringes which attach to tubing sets for connection to the patient's primary intravenous line. Drug delivery choices are easily selected and changed using front panel rotary switches. The selections are made directly in drug dosing units and, where appropriate, are related to patient body weight, thus eliminating tedious calculations. Total volume of drug delivered is displayed for both patient management and record keeping needs.

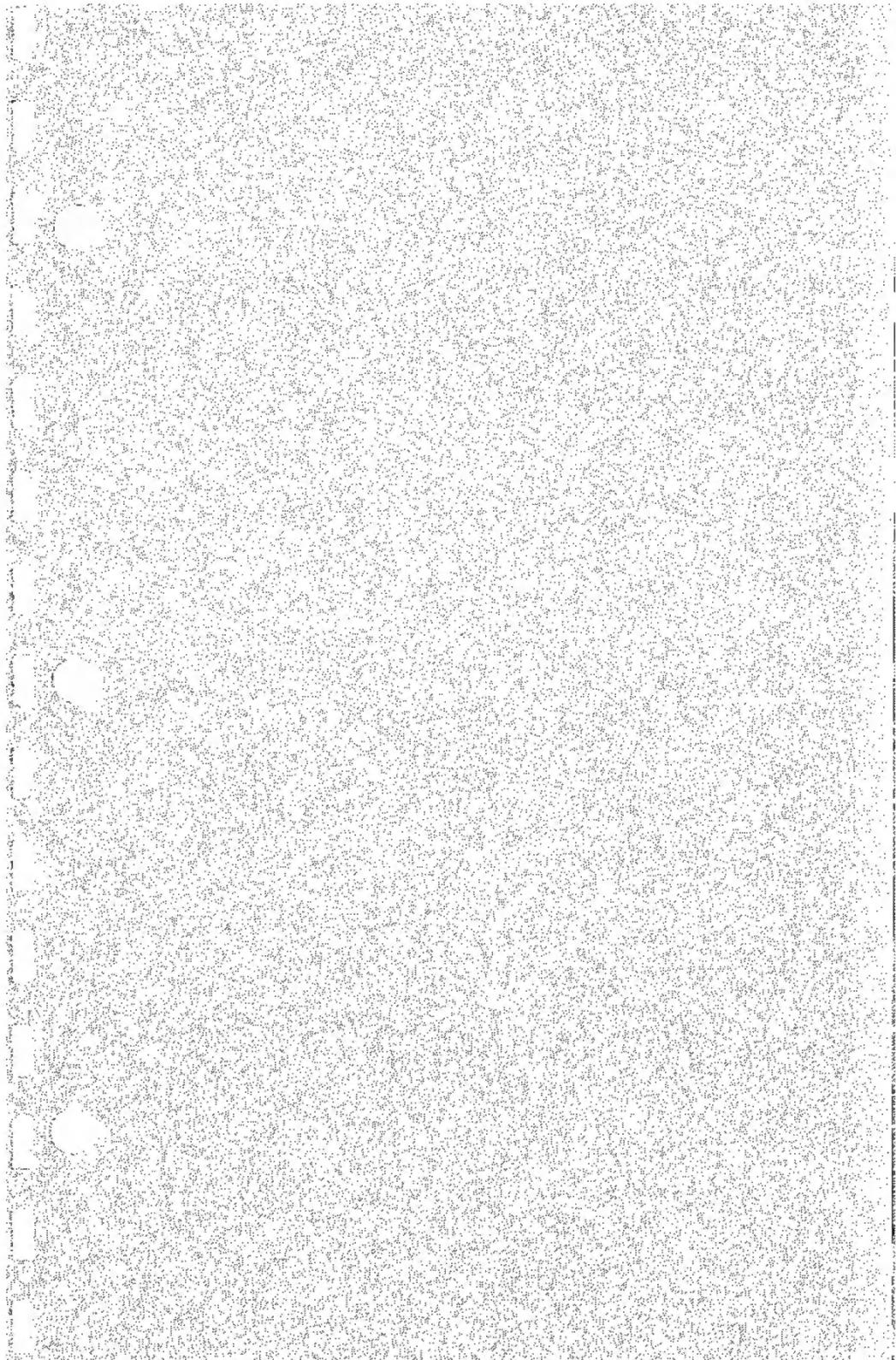
This lightweight battery operated pump is provided with a versatile mounting bracket that securely fastens the pump

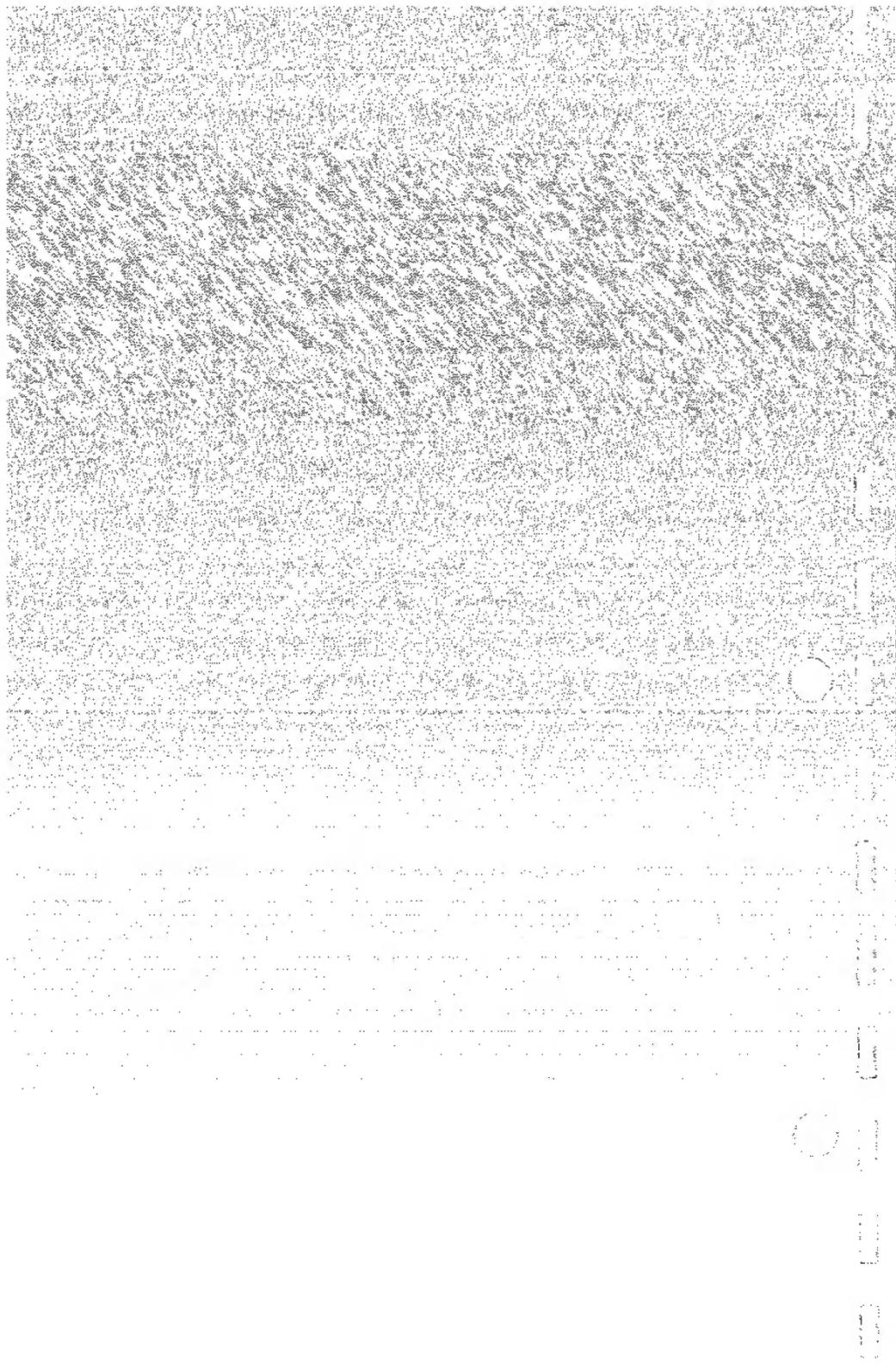
and provides good pump accessibility during use. The **INFUSO.R.** Pump and Smart Label System combine the flexibility of a general infusion device with the convenience of a drug specific infusion device to meet many intravenous delivery needs during anesthetic procedures.

U.S. Patent Nos. 4,804,368; 4,943,279; 4,544,369

B-D is a registered trademark of Becton-Dickinson and Company.

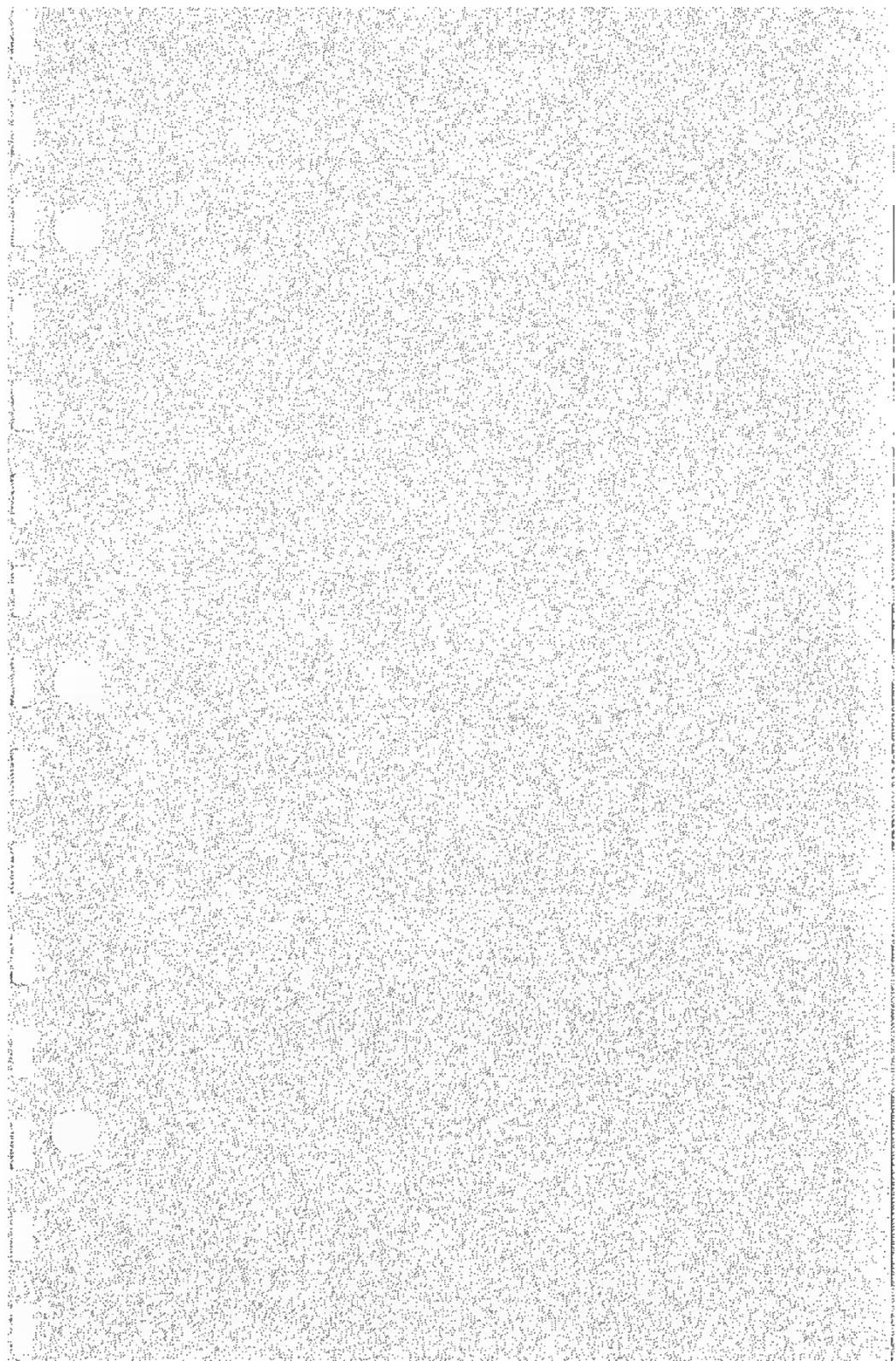
Monoject is a registered trademark of Sherwood Medical, Inc.





II. Principles of Operation

The **INFUSO.R.** Pump is a battery operated device that holds and empties disposable syringes in a controlled manner. A plastic holder accepts the syringe barrel. The syringe plunger is held and moved by a pusher assembly. The pusher engages a threaded leadscrew which is rotated by a reliable, efficient motor that is controlled and monitored by a microcomputer system. Magnetically coded labels attach to the pump front panel and are read by the microcomputer. The coded label tells the microcomputer the delivery rate selections available when that specific label is used with the pump. Rotary input switches, set by the user, select the drug delivery rate. Calculations are then performed by the microcomputer so that the drug is delivered as indicated. A force sensing system responds to overpressure in the fluid pathway and a position detector determines when the syringe needs refilling. The microcomputer controls the indicator lights and alarms and also displays the volume of drug delivered. The batteries are electronically monitored for a low power condition.





III. The Smart Label System

The convenience and flexibility of the *INFUSO.R.* Pump is provided by the Smart Label System. The Smart Label System is designed exclusively for use with the *INFUSO.R.* Pump and allows the pump to deliver many intravenous agents routinely administered during anesthetic procedures. The Smart Label System has the ability to redefine the rotary input switches of the *INFUSO.R.* Pump so that delivery rates appropriate to a given agent are available. In addition, the delivery functions of the switches may also be redefined by the Smart Label so that only delivery modes applicable to the agent are available. Your Baxter Healthcare Sales Representative can provide you with a complete list of available Smart Labels.

The Smart Labels are each color coded by drug class according to the ASTM Drug Label Color Standard. The class and color designations are as follows:

Narcotics	Light Blue
Muscle Relaxants	Fluorescent Red
Vasopressors	Violet
Hypotensive Agents	Violet/White Stripes
Induction Agents	Yellow
Other Agents	White

The Smart Label System provides for three different operating configurations of the front panel input switches depending on the drug being delivered. These three operating configurations are:

- Bolus and infusion delivery
- Infusion delivery without bolus
- Infusion delivery that is not based on body weight

Bolus and Infusion

For agents that are given as a loading or supplemental bolus and a continuous infusion, the Smart Label panel appears as shown in Figure 1. The top switch selects the pump infusion rate in units of mcg/kg/min. The middle switch provides Body Weight input for scaling the infusion rate. The third switch selects Bolus settings that are also scaled by body weight, given in units of mcg/kg. Examples of Smart Labels in this configuration are:

1. Alfentanil 500 mcg/mL
2. Atracurium 10 mcg/mL
3. Vecuronium 1 mg/mL
4. Esmolol 10 mg/mL

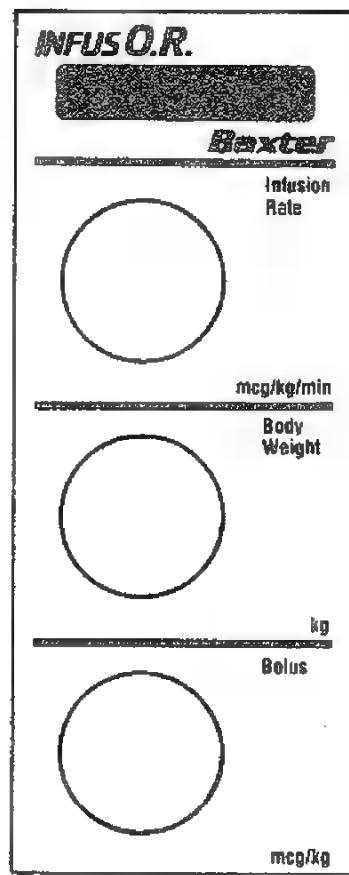


Figure 1

Infusion Delivery without Bolus

For agents that are given solely as a continuous infusion, the Smart Label panel appears as shown in Figure 2. The top switch selects the High Infusion Rate in mcg/kg/min. The middle switch selects Body Weight for scaling the infusion rate. The third switch selects Low Infusion Rate. In this configuration, only one infusion rate switch is active at any time. The other switch must be set to the zero position or a warning alarm will sound. Examples of Smart Labels in this configuration are:

1. Dopamine 4000 mcg/mL
2. Dobutamine 5000 mcg/mL
3. Nitroprusside 1000 mcg/mL
4. Nitroglycerin 1000 mcg/mL

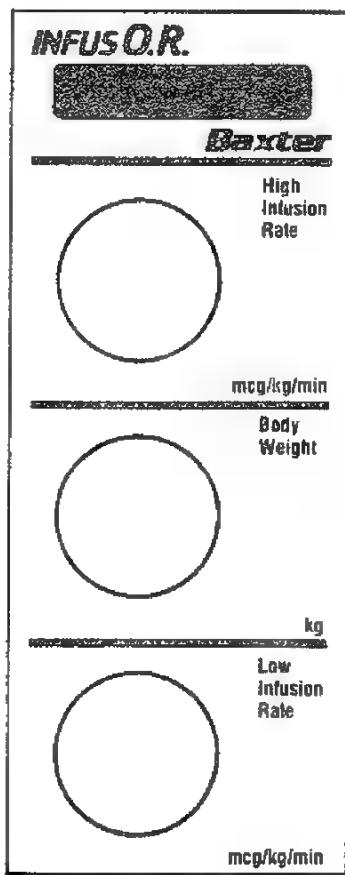


Figure 2

Infusion Delivery not Based on Body Weight

For agents that are given as a continuous infusion not based on body weight, the Smart Label panel appears as shown in Figure 3. The top switch selects High Infusion Rates usually in mcg/min. The middle switch is labeled "Not Active" and has no effect on pump rate delivery. The third switch selects Low Infusion Rates. Examples of Smart Labels in this configuration are:

1. Epinephrine 20 mcg/mL
2. Isoproterenol 20 mcg/mL
3. General mL/hr

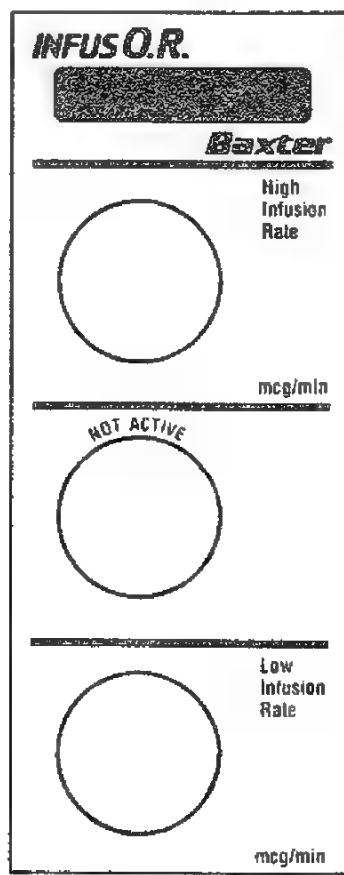


Figure 3

Drug Concentration and Syringe Size

Each Smart Label lists the drug concentration for use in the *INFUSO.R.* Pump along with dilution instructions for obtaining this concentration. The dilution instructions are printed on the back of the Smart Label. In addition, the syringe size to be used with the Smart Label is also listed on the label.

**WARNING: THE PROPER DRUG
CONCENTRATION AND SYRINGE
SIZE MUST BE USED FOR EACH
SMART LABEL OR INACCURATE
DOSING WILL OCCUR.**

Refer to the Smart Label Instruction Sheet provided with each Smart Label for additional information. A representative Smart Label Instruction Sheet is provided in Attachment XIII of this manual for reference purposes only. Always refer to the Instruction Sheet provided with each Smart Label at the time of use.

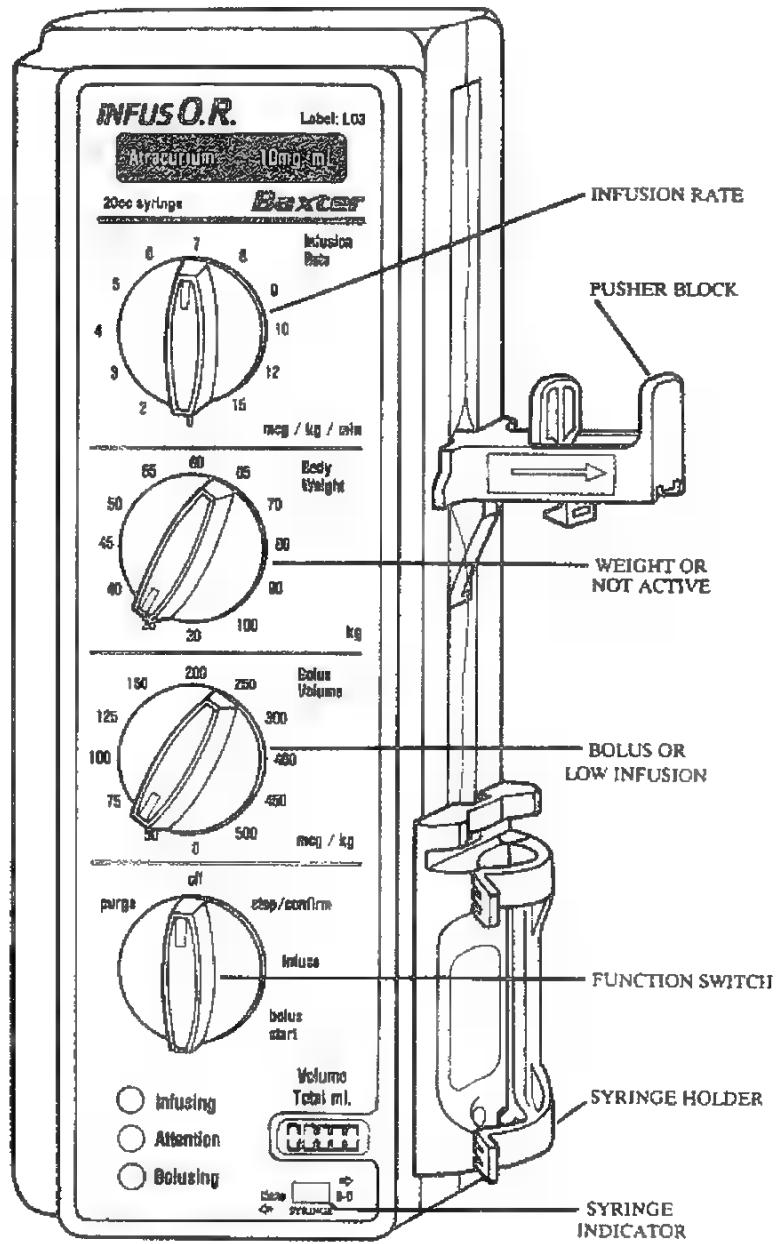
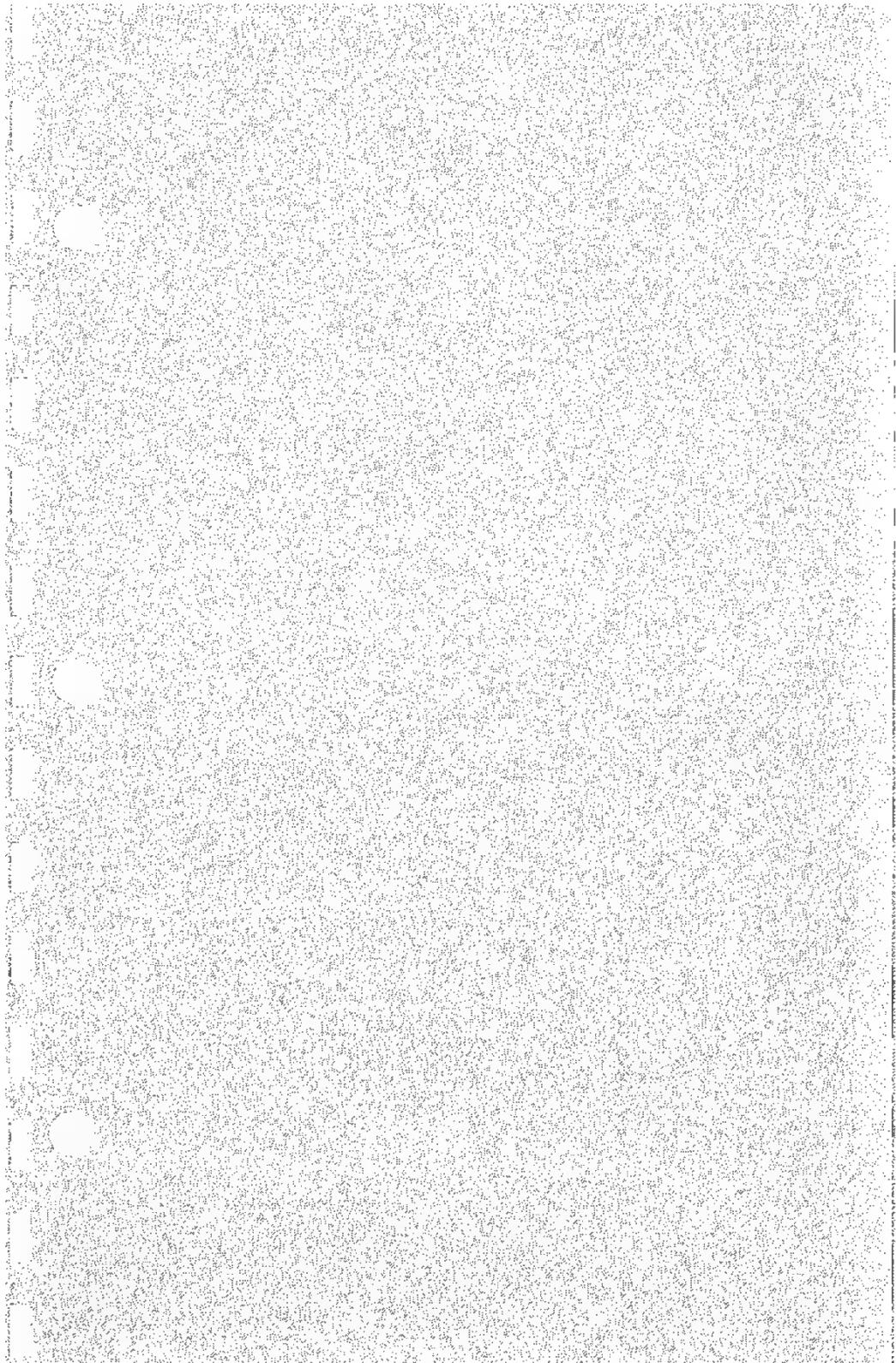
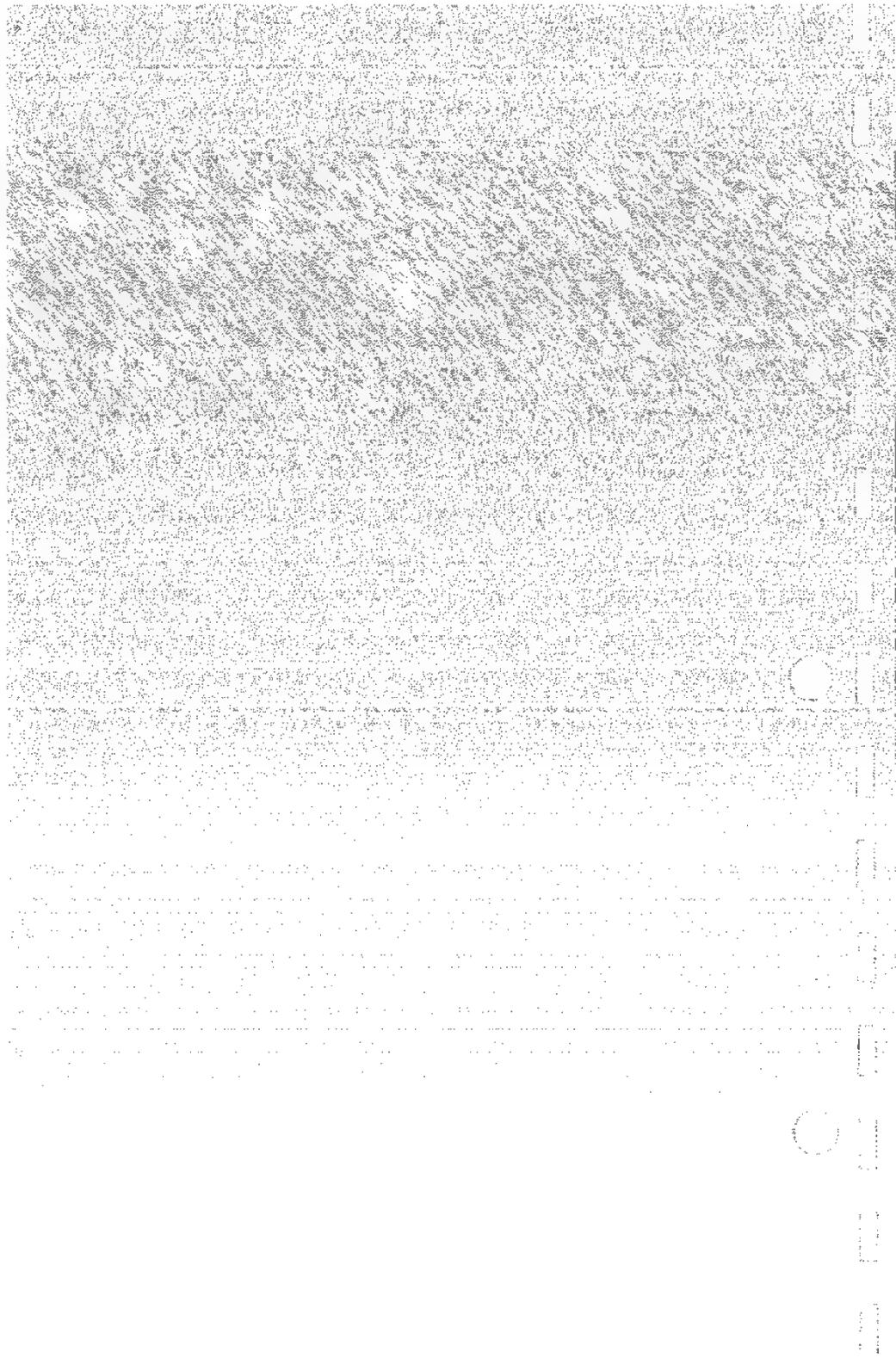


Figure 4





IV. Description of Features

Smart Label

The Smart Labels allow delivery of a variety of narcotic, muscle relaxant, and vasoactive drugs. Applicable bolus volume, body weight, and infusion rate settings for each drug are noted on the label. Each label bears a unique identification code and defines the appropriate drug concentration and syringe size to be used. A Smart Label must be attached to the face of the pump for pump operation to commence.

Function Switch

The Function switch is used to choose among five operating states. **WHEN THE SWITCH IS MOVED TO "OFF", ALL POWER IS OFF AND ALL INTERNAL MEMORY IS LOST.** When held in PURGE, the pump will deliver at approximately three (3) or six (6) milliliters/minute with a 20 cc or 60 cc syringe, respectively. The position is "momentary" so that, upon release, the switch returns to OFF. When moved to STOP/CONFIRM the infusion is suspended and any initiated bolus is permanently terminated. Total dose memory is retained. In the INFUSE position, the pump will infuse at the rate indicated by the Infusion Rate switch.

If moved to the BOLUS START position and held for one second, a short audible tone will be heard after which a bolus is delivered at the appropriate rate. The BOLUS START position is also "momentary" and the switch will return to INFUSE when released.

Once initiated, the bolus selected will be given even if the Bolus switch is changed to a different selection.

Infusion Rate Switch

The Infusion Rate switch sets the infusion rate in micrograms per kilogram per minute to be infused when the Function switch is in INFUSE. Available settings are identified on the Smart Label for the drug to be infused.

Body Weight Switch or Not Active

The Body Weight switch selects the weight adjustment factor in kilograms used for both the infusion rate and bolus calculations. The choices are 30, 35, 40, 45, 50, 55, 60, 65, 70, 80, 90 and 100 kilograms (kg). For drugs that are not given as a function of body weight, the Smart Label defines this switch as NOT ACTIVE.

Bolus Switch or Low Infusion Rate Switch

The Bolus switch selects the bolus that will be infused when initiated. Available settings are identified on the Smart Label for the drug to be infused. For drugs that are not indicated for bolus delivery, this switch is redefined by the Smart Label as a Low Infusion Rate switch. This Low Infusion Rate switch works similarly to the Infusion Rate switch.

Infusing Light

The Infusing Light will flash when an infusion rate other than "0" is chosen and the Function switch is in INFUSE. This light indicates that a normal infusion is occurring.

Bolusing Light

The Bolusing Light will flash during the time that a bolus is being delivered.

Attention Light

The Attention Light will flash when an attention condition occurs. The attention conditions are low battery, end of syringe, occlusion, and internal fault. The Digital Display will show which condition exists.

Digital Display

The Digital Display gives important information about the *INFUSO.R.* pump's status. When the Function switch is first set to STOP/CONFIRM, the Display shows the label identification code for the applied Smart Label. When bolusing, the Display will progress upward from zero to the selected bolus in mL increments as the delivery occurs. During normal infusion, the Display gives the total amount of drug in mL delivered since the pump was last turned "on". Turning the Function switch to OFF clears the Digital Display.

NOTE: When the function switch is moved to OFF, all power is off and all internal memory is lost.

During an attention condition, the Display will show which condition exists as shown below.

Display	Condition Description
LO BA	Low Battery
EOS	End of Syringe
OCC	Occlusion

LO BA	Low Battery
EOS	End of Syringe
OCC	Occlusion

Refer to Section VIII for additional information on these attention conditions.

Syringe Manufacturer Selector Switch

The Syringe Manufacturer Selector switch is set to identify use of either B-D or Monoject syringes.

Audio Indicators

Audio Indicators signify several pump conditions. These are occlusion, end of syringe, internal fault, bolus initiation, improper switch position, and missing Smart Label.

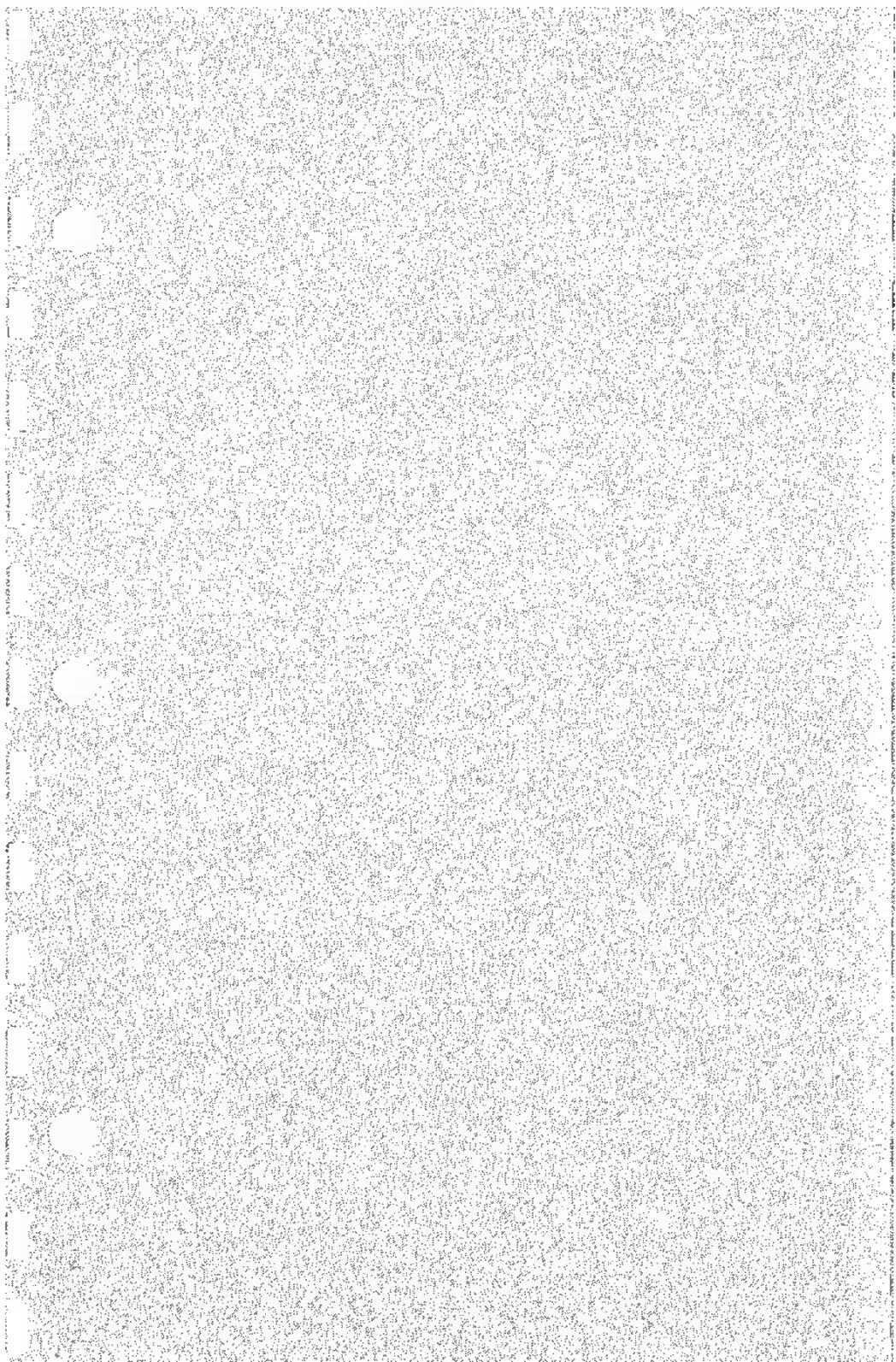
Both the Occlusion and End of Syringe Alarms are identical pulsating audible beeps. Nonetheless, they are independently sensed. An Occlusion Alarm occurs when the pump cannot overcome excessive flow path resistance such as closed stopcocks or other obstructions. An End of Syringe alarm occurs when approximately one milliliter remains in the syringe. The existing condition can be determined by reading the Digital Display. An Internal Fault causes the audio alarm and all lights to come on continuously and simultaneously. A single short audible

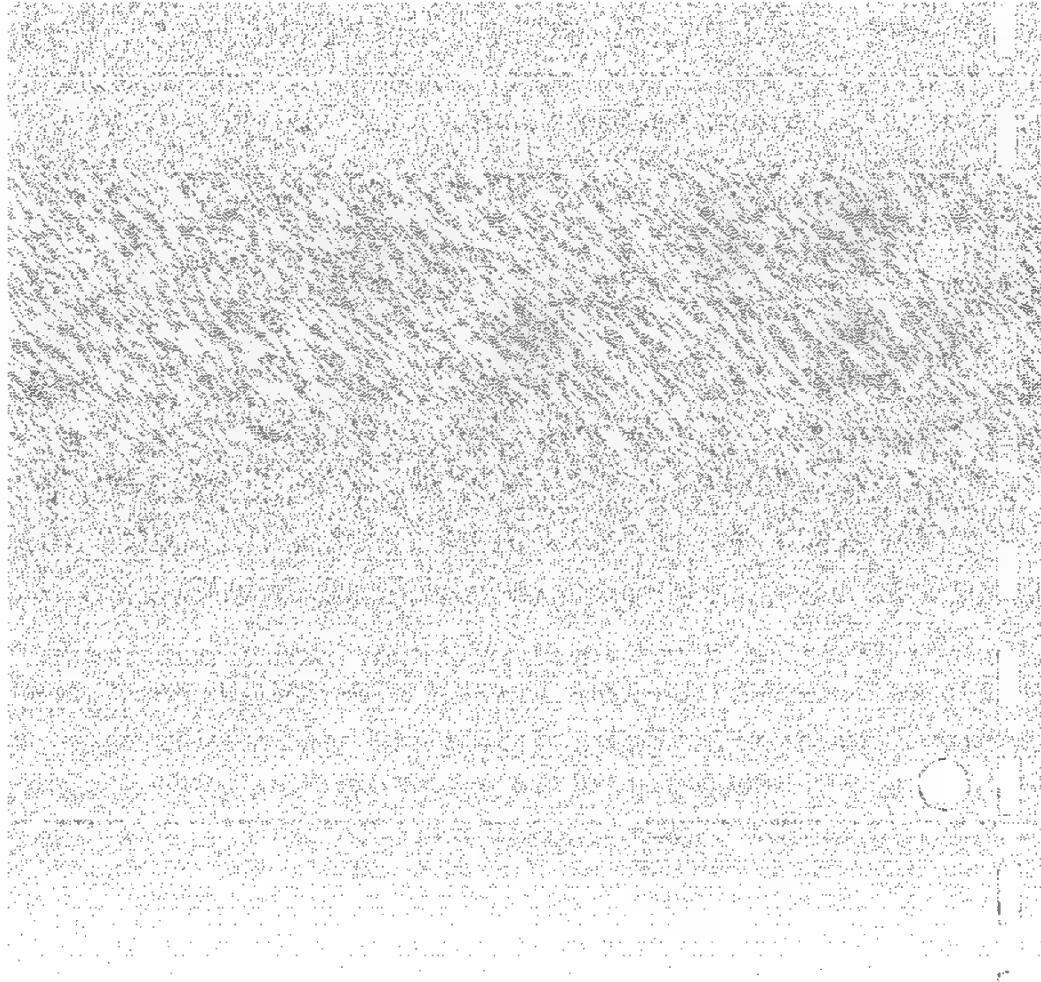
beep occurs upon each successful bolus initiation. If any switch is improperly placed between active positions, three short audible beeps will occur. Refer to Section VIII of this Manual for additional information on each audible alarm condition.

Mounting Bracket

The pump is supplied with a mounting plate preassembled to the rear face. It is recommended that this plate be used in conjunction with the Mounting Bracket, also supplied, for maximum convenience, safety, and security. The Mounting Bracket will attach to most IV poles.







$$= \frac{1}{2} \partial_{\mu} \partial^{\mu} \phi$$

2

V. INSTRUCTIONS FOR USE - GENERAL

Accepted principles and practices of IV therapy should be followed for all administrations. The rate and bolus selections on the Pump's Smart Label System should allow convenient, appropriate drug delivery regimens. Actual dose requirements must be carefully determined by the physician based on the individual response of each patient. Careful review of these instructions and thorough familiarization with both the Pump and the drug is recommended before use with patients.

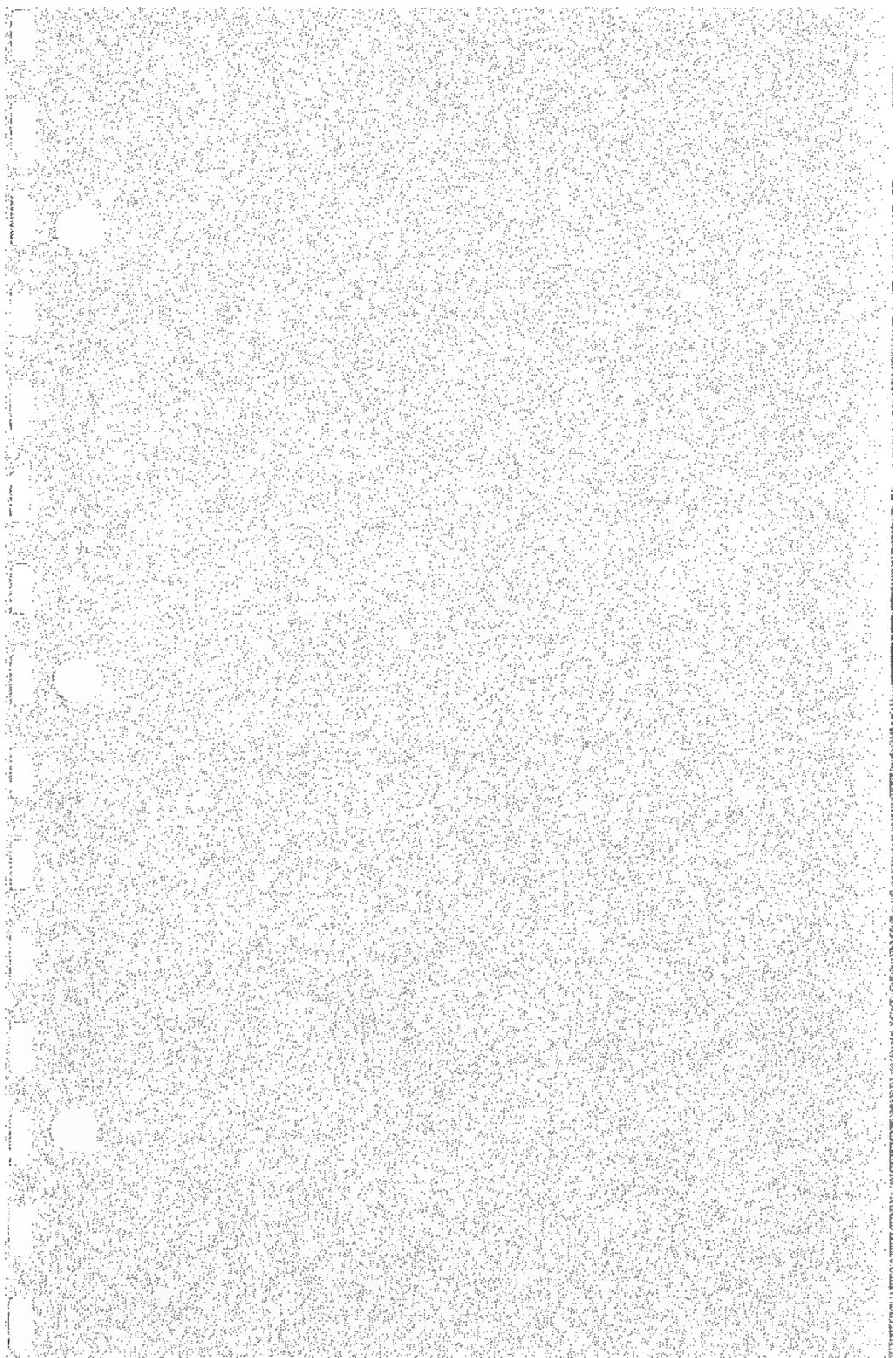
**WARNING: USE ONLY B-D OR MONOJECT
20CC OR 60CC PLASTIC
DISPOSABLE SYRINGES AS
INDICATED ON THE SMART
LABEL. USE OF OTHER
SYRINGES OR THE WRONG SIZE
SYRINGE WILL RESULT IN
INACCURATE DOSING.**

**WARNING: THE INFUSO.R. PUMP IS
DESIGNED FOR THE OPERATING
ROOM DELIVERY OF
PARENTERAL FLUIDS UNDER
CONSTANT SURVEILLANCE BY
INDIVIDUALS TRAINED IN THE
ADMINISTRATION OF THESE
AGENTS. BAXTER HEALTHCARE
CORPORATION DOES NOT
RECOMMEND THE USE OF THIS
PUMP WHEN SURVEILLANCE IS
NOT CONTINUAL.**

**WARNING: ALL DRUG WARNINGS,
PRECAUTIONS, AND
CONTRAINdicATIONS SHOULD
BE CONSIDERED WHEN USING
THIS PUMP.**

**WARNING: USE OF THE INFUSO.R. PUMP
NEAR ELECTRIC FIELDS,
MAGNETIC FIELDS, OR
RADIATION (E.G. ELECTROSUR-
GICAL UNITS, MAGNETIC
RESONANCE IMAGING
MACHINES, X-RAY MACHINES)
IS NOT RECOMMENDED. SUCH
USE MAY RESULT IN DEVICE
MALFUNCTION. THE
INFUSO.R. PUMP HAS PASSED
ESD/EMI/EMISSION TESTING PER
TEST SPECIFICATION**

#MDS - 201 - 0004 OF THE U.S.
DEPARTMENT OF HEALTH
AND HUMAN SERVICES. IT HAS ALSO
PERFORMED SATISFACTORILY
DURING ESU TESTING. CONTACT
YOUR BAXTER SALES REPRESENTA-
TIVE IF ADDITIONAL
INFORMATION IS REQUIRED.



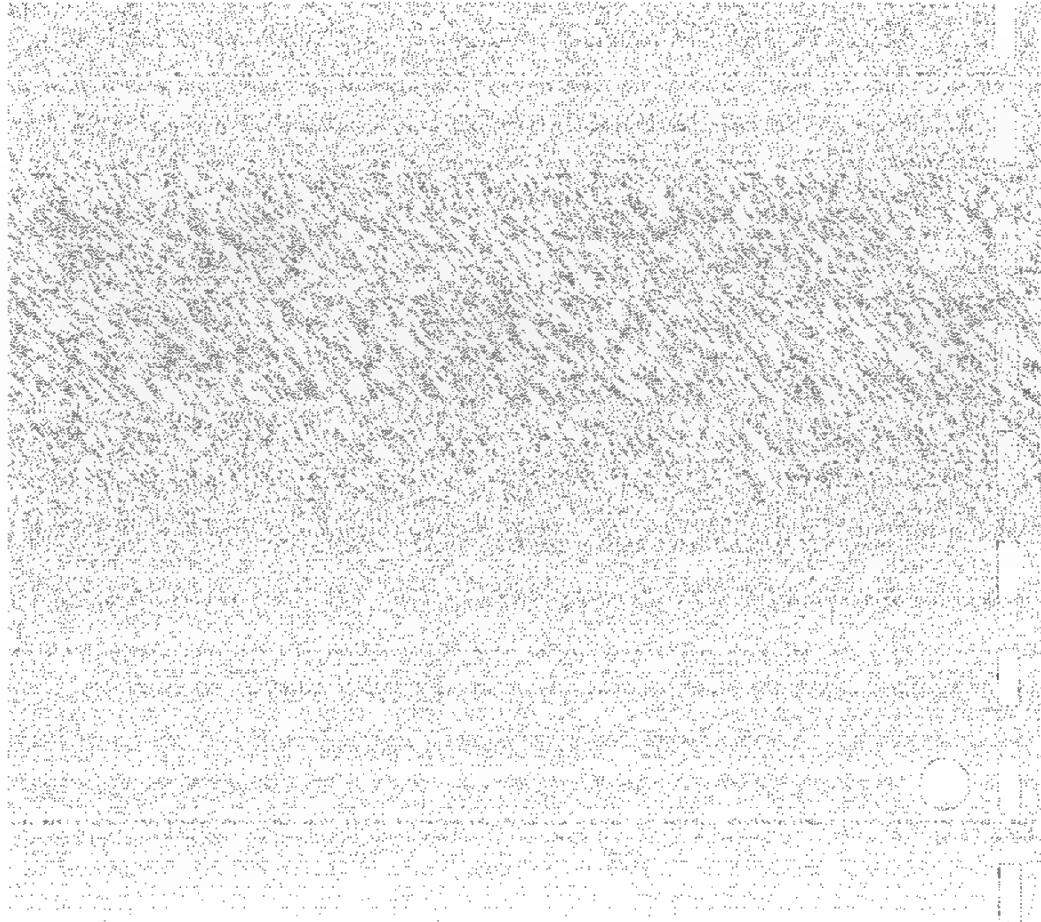


Figure 1. A high-contrast, black and white image showing a dense, textured surface, possibly a wall or floor, with a prominent diagonal grain. A small, circular hole is visible in the upper right corner.

and the corresponding image in the original image set. The image in the original image set is a high-contrast, black and white image showing a dense, textured surface, possibly a wall or floor, with a prominent diagonal grain. A small, circular hole is visible in the upper right corner.

Figure 1 shows a high-contrast, black and white image of a textured surface. The surface has a prominent diagonal grain. A small, circular hole is visible in the upper right corner. The image is grainy and has a high-contrast, black and white appearance.

Figure 2 shows a high-contrast, black and white image of a textured surface. The surface has a prominent diagonal grain. A small, circular hole is visible in the upper right corner. The image is grainy and has a high-contrast, black and white appearance.

Figure 3 shows a high-contrast, black and white image of a textured surface. The surface has a prominent diagonal grain. A small, circular hole is visible in the upper right corner. The image is grainy and has a high-contrast, black and white appearance.

Figure 4 shows a high-contrast, black and white image of a textured surface. The surface has a prominent diagonal grain. A small, circular hole is visible in the upper right corner. The image is grainy and has a high-contrast, black and white appearance.

Figure 5 shows a high-contrast, black and white image of a textured surface. The surface has a prominent diagonal grain. A small, circular hole is visible in the upper right corner. The image is grainy and has a high-contrast, black and white appearance.

Figure 6 shows a high-contrast, black and white image of a textured surface. The surface has a prominent diagonal grain. A small, circular hole is visible in the upper right corner. The image is grainy and has a high-contrast, black and white appearance.

VI. INSTRUCTIONS FOR USE - SYSTEM SETUP

When setting up the ***INFUSO.R.*** Pump:
(refer to Figure 4)

1. Install the Smart Label for the drug to be infused. Set the Function switch to the STOP/CONFIRM position. Confirm that the label identification code shown on the Digital Display matches the code on the Smart Label. The code is located in the upper section of the Smart Label.

**WARNING: IF THE LABEL IDENTIFICATION
CODE ON THE DISPLAY DOES
NOT MATCH THE CODE ON THE
SMART LABEL, DO NOT
OPERATE THE PUMP.**

2. Fill a 20cc or 60cc Monoject or B-D syringe with the amount of drug required. The syringe size to be used for each Smart Label is shown on the upper section of the label. Confirm that the concentration of the infusate matches the drug concentration noted on the Smart Label.

**WARNING: CONCENTRATION OF THE
INFUSATE MUST MATCH THE
DRUG CONCENTRATION NOTED
ON THE SMART LABEL OR
INACCURATE DOSING WILL
RESULT.**

3. Attach an appropriate infusion set to the syringe.

**WARNING: USING SETS OTHER THAN
THOSE RECOMMENDED
BY BAXTER HEALTHCARE
CORPORATION MAY RESULT
IN NUISANCE ALARMS OR
REQUIRE EXCESS PRIMING
VOLUME. THIS EXCESS
VOLUME COULD CAUSE
SIGNIFICANT EFFECTS DURING
SYRINGE CHANGES OR OTHER
MANIPULATIONS.**

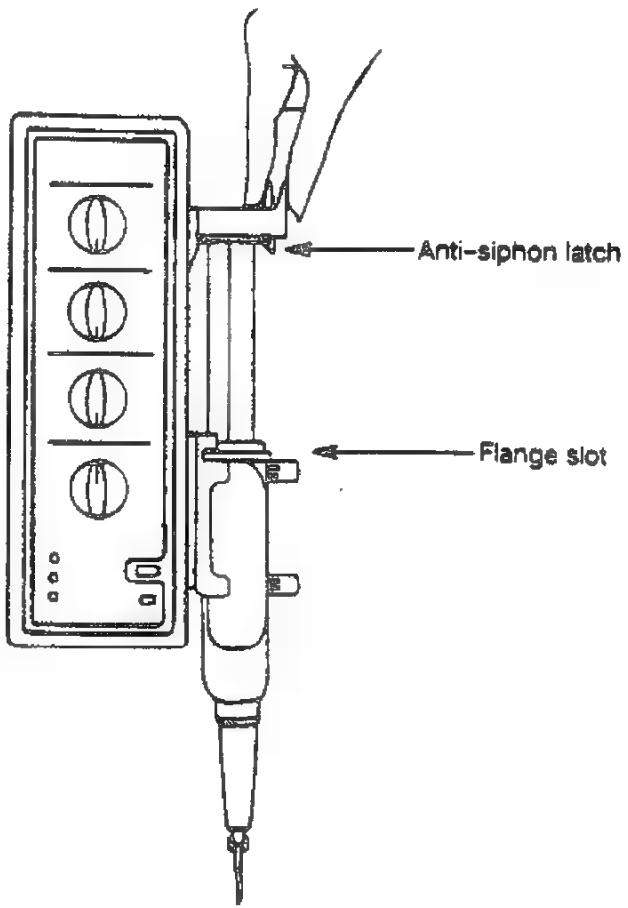
4. Attach a port puncturing needle to the distal end of the set, if required.
5. Eliminate all air from the fluid path.

NOTE: Refer to Figure 5 for steps 6-8.

6. Reset the Pusher block to the pump's top end by moving the Pusher block upward while squeezing the Release Lever with thumb and forefinger.

NOTE: Squeeze the Release Lever fully prior to movement for smoothest operation.

7. Place the syringe barrel into the Syringe Barrel Holder.



**WARNING: ASSURE THE SYRINGE BARREL
FLANGE IS PROPERLY INSERTED
INTO THE HOLDER'S NOTCH OR
UNCONTROLLED EMPTYING
MAY OCCUR.**

FIGURE 5

8. Move the Pusher downward until it touches the syringe plunger, then release the Lever so that the Anti-Siphon Latch engages the syringe plunger flange.

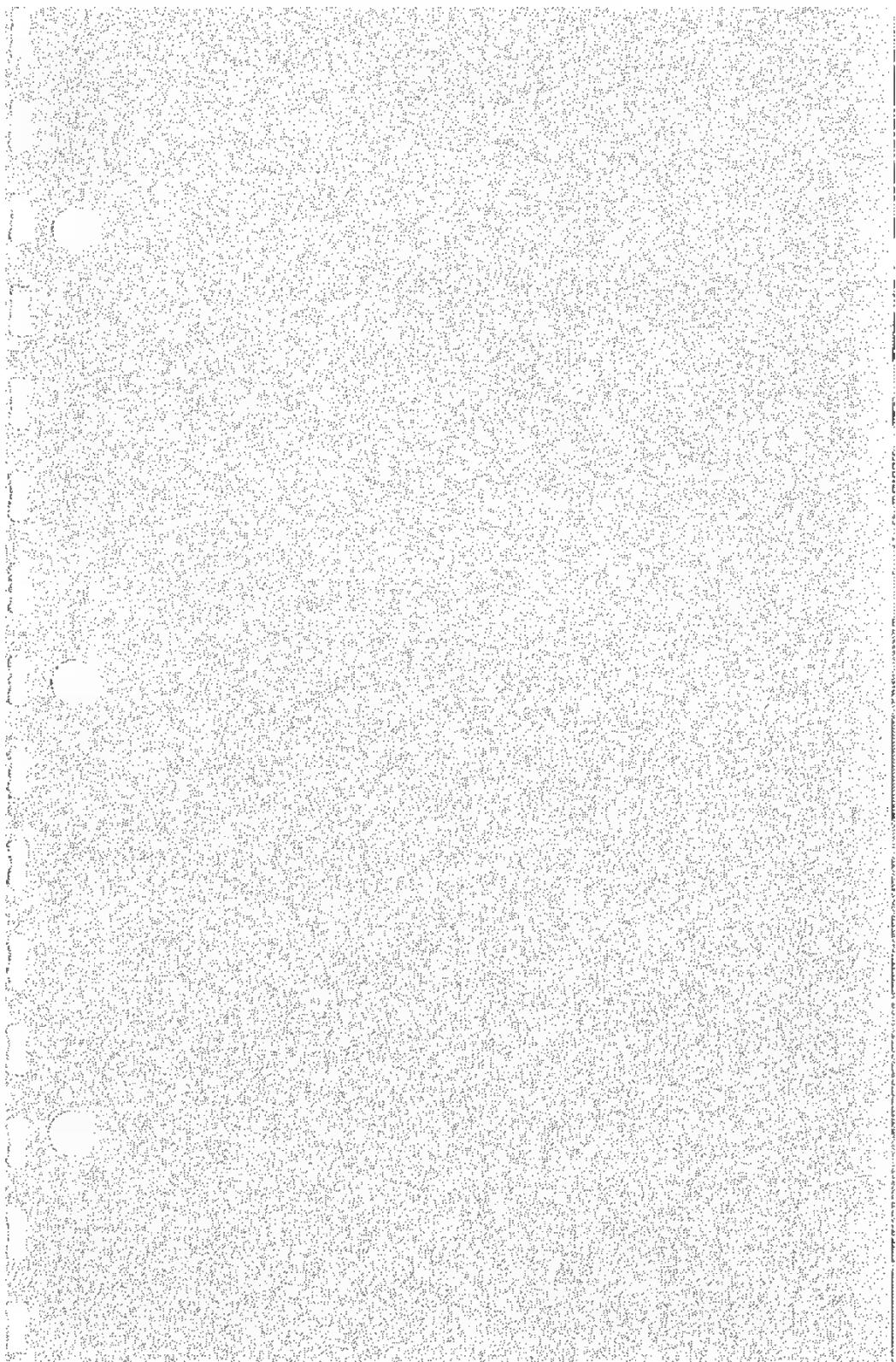
**WARNING: IF THE PLUNGER FLANGE IS
NOT PROPERLY ENGAGED BY
THE ANTI-SIPHON LATCH,
UNCONTROLLED SYRINGE
EMPTYING MAY RESULT.**

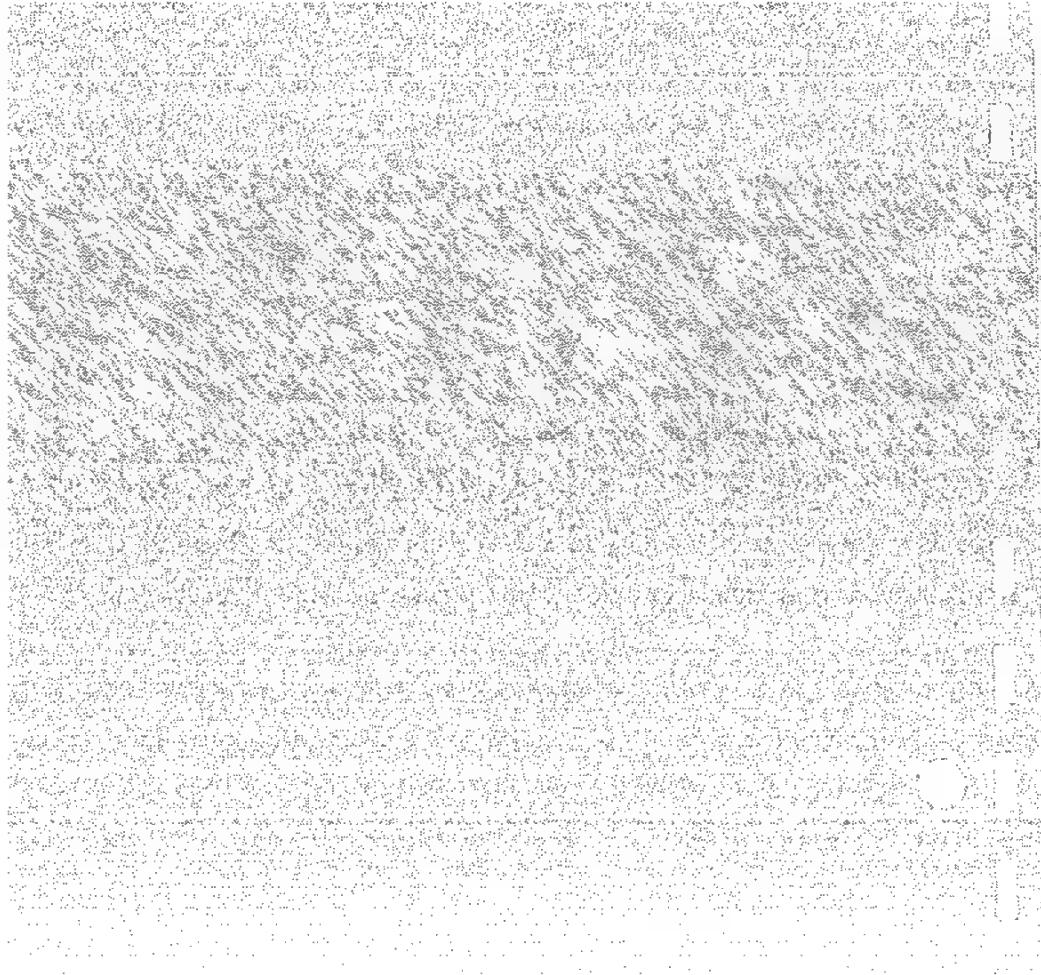
9. While observing the fluid outlet, turn the Function switch to PURGE until fluid flow occurs.

**WARNING: DO NOT USE PURGE POSITION
WHILE CONNECTED TO THE
PATIENT.**

10. Connect the fluid outlet to the patient's primary IV line or catheter.

**WARNING: WHEN INFUSING INTO PRIMARY
LINE PORTS, THE PRIMING
VOLUME DOWNSTREAM OF THE
PORT MAY CAUSE "DELAY
EFFECTS" AND "BOLUS
EFFECTS" IN DRUG DELIVERY.
USE THE PORT OR FLASHBALL
SITE NEAREST THE PATIENT TO
MINIMIZE THESE EFFECTS.**





1. *What is the relationship between the number of hours worked and the number of hours slept?*

2. *What is the relationship between the number of hours worked and the number of hours slept?*

3. *What is the relationship between the number of hours worked and the number of hours slept?*

4. *What is the relationship between the number of hours worked and the number of hours slept?*

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9. *What is the relationship between the number of hours worked and the number of hours slept?*

10. *What is the relationship between the number of hours worked and the number of hours slept?*

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VII. INSTRUCTIONS FOR USE - PUMP OPERATION

The Smart Label System defines the *INFUSO.R.* Pump input switch configuration and the specific settings for each switch. Once the system is properly prepared, as outlined by the Smart Label Instruction Sheet and Section VI of these instructions, the Pump is operated as described below.

Set the Syringe Manufacturer Selector switch to the proper selection. The switch is located below the digital display.

**WARNING: DUE TO DIFFERENCES IN
SYRINGE DIAMETERS, THE
VOLUME DELIVERY IS
AFFECTED BY CHOOSING
EITHER B-D OR MONOJECT
SYRINGES. THIS DIFFERENCE IS
MOST PRONOUNCED (13%)
WHEN USING 20 CC SYRINGES
AND IS NEGLIGIBLE WITH 60 CC
SYRINGES. FOR PROPER
DELIVERY, ASSURE CORRECT
SWITCH POSITION.**

NOTE: Changing the Syringe Manufacturer Selector switch during pump operation will cause the pump to alarm. The pump must be turned off to clear the alarm.

Smart Label Verification

If not already confirmed, verify that the identification code on the display matches the label identification code shown below the Smart Label drug name.

WARNING: IF THE LABEL IDENTIFICATION CODE ON THE DISPLAY DOES NOT MATCH THE SMART LABEL IDENTIFICATION CODE, DO NOT USE THE PUMP.

Body Weight Selection

For drugs that are delivered as a function of body weight, select the body weight to be used by the Pump's computer for dosage calculations. Rotate the Body Weight switch to the value closest to the patient's weight.

Infusion Rate Selection

To deliver a constant infusion of the drug, rotate the Infusion Rate switch to the desired rate and move the Function switch to INFUSE. The green infusion light will flash to show that a normal infusion is occurring. The digital display will begin incrementing in milliliters the amount of drug delivered. To change the rate, simply rotate the infusion rate switch to a new setting.

For Smart Labels that have a High Infusion Rate setting and a Low Infusion Rate setting, only one rate setting is allowed at any time. Therefore, if a Low Infusion Rate is set, the High Infusion Rate switch must be set to zero or the pump will give a warning alarm.

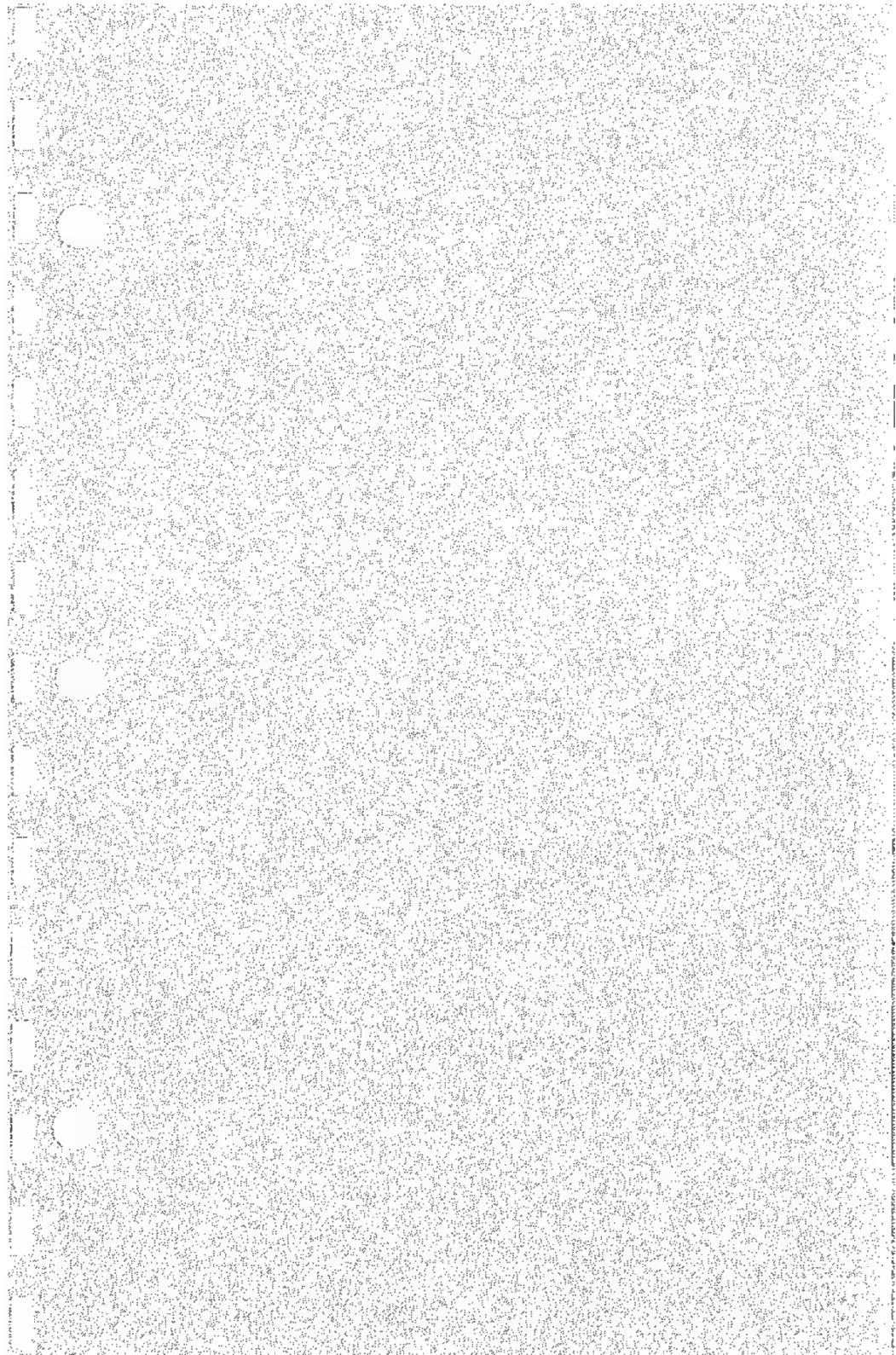
The same applies to the Low Infusion Rate when setting a High Infusion Rate delivery. To stop an infusion, turn the active rate switch to "0", or turn the function switch to the STOP/CONFIRM position.

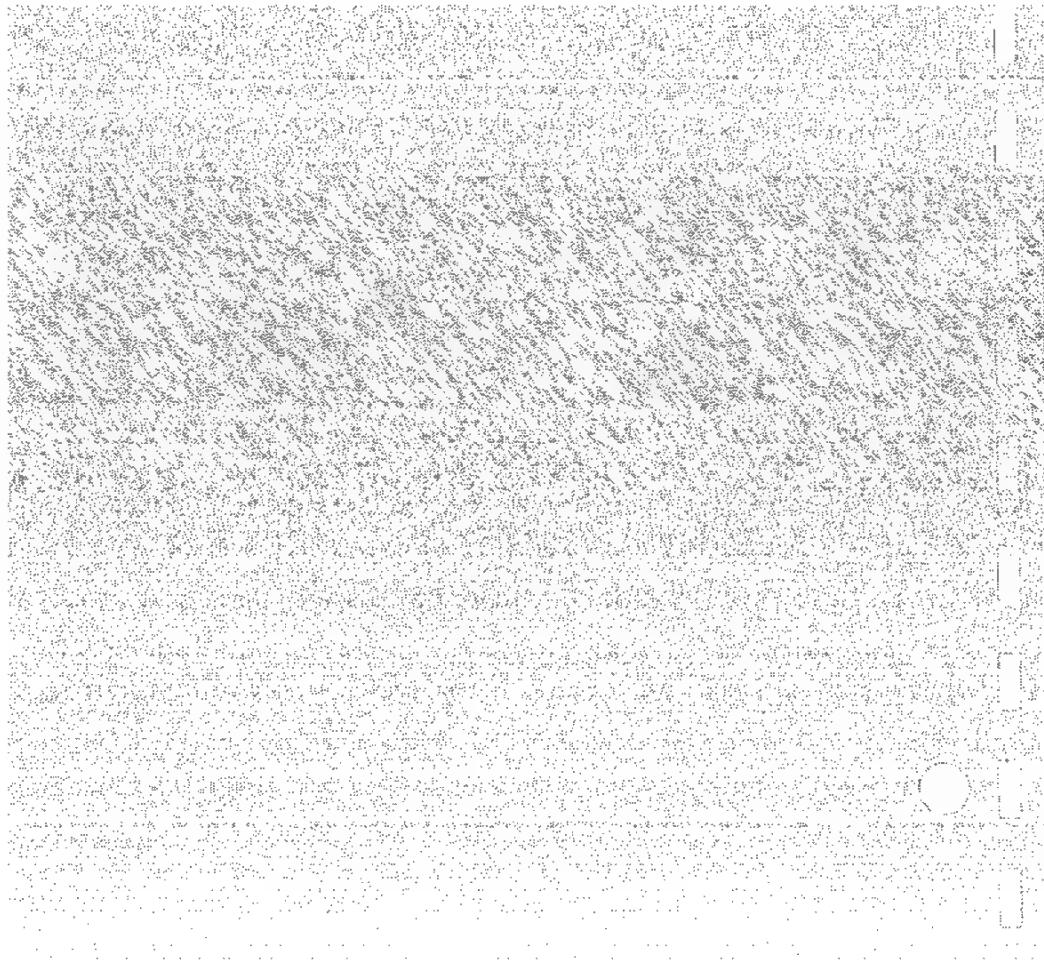
Loading or Supplemental Bolus Administration

To administer a loading or supplemental bolus dose, choose the desired dose on the Bolus switch and rotate the Function switch to the BOLUS START position. When a short audible beep is heard, release the Function switch. The audible beep indicates successful bolus initiation. The bolusing light will flash to indicate normal bolus delivery. The digital display will begin incrementing in milliliters as the bolus is delivered to show the status of the present bolus.

To stop a bolus delivery, rotate the Function switch to the STOP/CONFIRM position. This will permanently terminate the current bolus. Once a bolus is initiated, the Bolus switch may be changed to a new setting in anticipation of future need. The current bolus will be unaffected and will be delivered as initially selected. Changes to the Body Weight switch will also not affect a bolus in progress.

For drugs that are not given as loading or supplemental boluses, the Smart Label redefines the Bolus switch as a Low Infusion Rate switch, therefore preventing bolus delivery of these agents. Rotating the Function switch to the BOLUS START position will have no affect on pump operation for delivery of these agents.





and the number of the day. The day of the week is determined by the day of the month, the day of the year, and the year.

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VIII. WARNING INDICATORS

The following actions should be taken when audible warnings occur.

1. End of Syringe or Occlusion

A delivery system occlusion or an empty syringe is indicated by a pulsating audible alarm and flashing attention light. The display will indicate which condition exists.

If the display reads EOS, the syringe is nearly empty and must be refilled or replaced. To do so, turn the Function switch to STOP/CONFIRM, then clamp the tubing set.

WARNING: ASSURE THAT THE EXTENSION SET IS CLAMPED BEFORE DISCONNECTING THE SYRINGE. IF THE EXTENSION SET IS NOT CLAMPED, THE VOLUME IN THE TUBING SET MAY BE DELIVERED INTO THE PATIENT BY GRAVITY. THIS COULD RESULT IN SIGNIFICANT ADVERSE EFFECTS.

Remove the syringe by first resetting the Pusher then removing the syringe barrel from the Holder. Disconnect the syringe from the tubing set and reconnect a properly prepared syringe. Repeat the system set-up steps for reinserting the syringe. Unclamp the tubing set, then return the Function switch to INFUSE to resume the infusion.

If the display reads OCC, an occlusion in the delivery system exists. Turn the Function switch to STOP/CONFIRM, then determine the cause and location of the occlusion.

**WARNING: TO REDUCE THE RISK OF
STORED FLUID BEING INFUSED
AFTER AN OCCLUSION OCCURS,
THE PRESSURE MUST BE
RELIEVED PRIOR TO FREEING
THE OCCLUSION. DO THIS BY
RESETTING THE PUSHER
AND/OR DISCONNECTING THE
SYSTEM ABOVE THE
OCCLUSION.**

Correct the occlusion, then return the Function switch to INFUSE to resume the infusion.

NOTE: If an Occlusion or End of Syringe alarm occurs while bolusing, the bolus delivery will be permanently terminated. To resume and complete the current bolus, note the digital display setting before turning the Function switch to STOP/CONFIRM. After rectifying the alarm condition, initiate a new bolus for the balance of the dose.

2. Low Battery

If the attention light flashes without an audible alarm, then a low battery condition exists. Check the display for

LO BA to verify this condition, then replace the batteries with four C-size alkaline cells before the next procedure. The present administration may usually be safely completed since the batteries should last several hours after the alarm is first indicated.

NOTE: When the batteries are removed, all internal memory is lost.

NOTE: Battery life will be significantly affected by bolus duration, backpressure required, and audible alarm duration.

3. Internal Fault

An Internal Fault alarm is signified by the audible alarm, all lights coming on continuously, and all pumping operation stops. This alarm is caused by three different conditions: Syringe Manufacturer Selector switch moved, Smart Label removed, or internal electronic failure. Which of these conditions exists must be determined and the appropriate action taken.

If the Syringe Manufacturer Selector switch was changed during operation, turn the Function switch to OFF, set the switch to its proper position and resume operation.

Should the Smart Label become detached during use, turn the Function switch to OFF, reattach the label and resume operation.

If the cause of the alarm cannot be determined, the pump should be taken out of service and returned for repair.

NOTE: The pump should be left off for a few seconds before resuming operation to allow all internal memory to clear. Otherwise, the internal fault alarm may occur.

4. Improper Switch Position

If any switch is left in or held in a position between actual selections for over one-half second, the pump will alarm with three short audible beeps. The pump will continue to infuse at the previously chosen rate. Reposition the switch to the proper location to terminate the alarm.

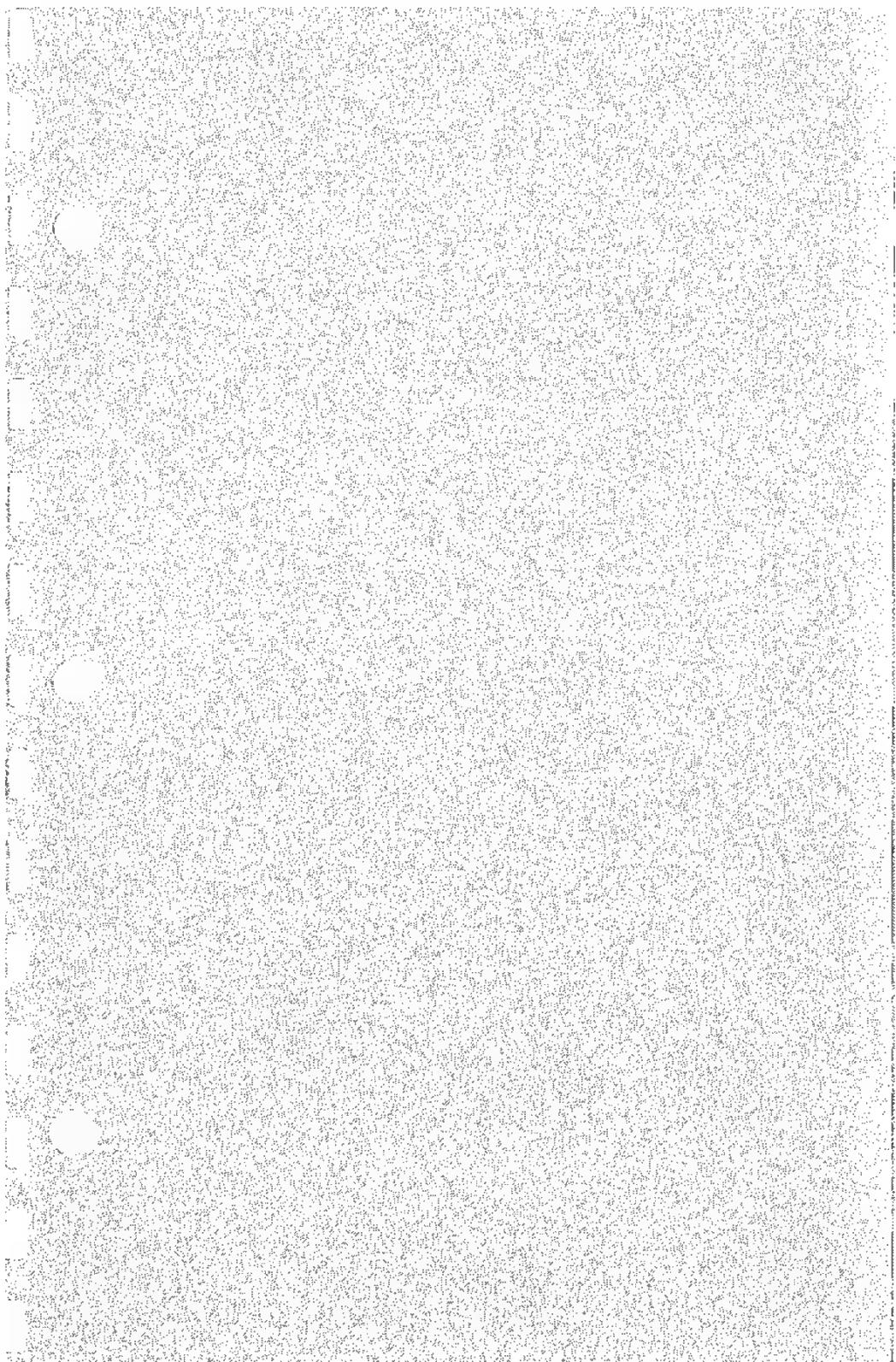
5. Missing Smart Label

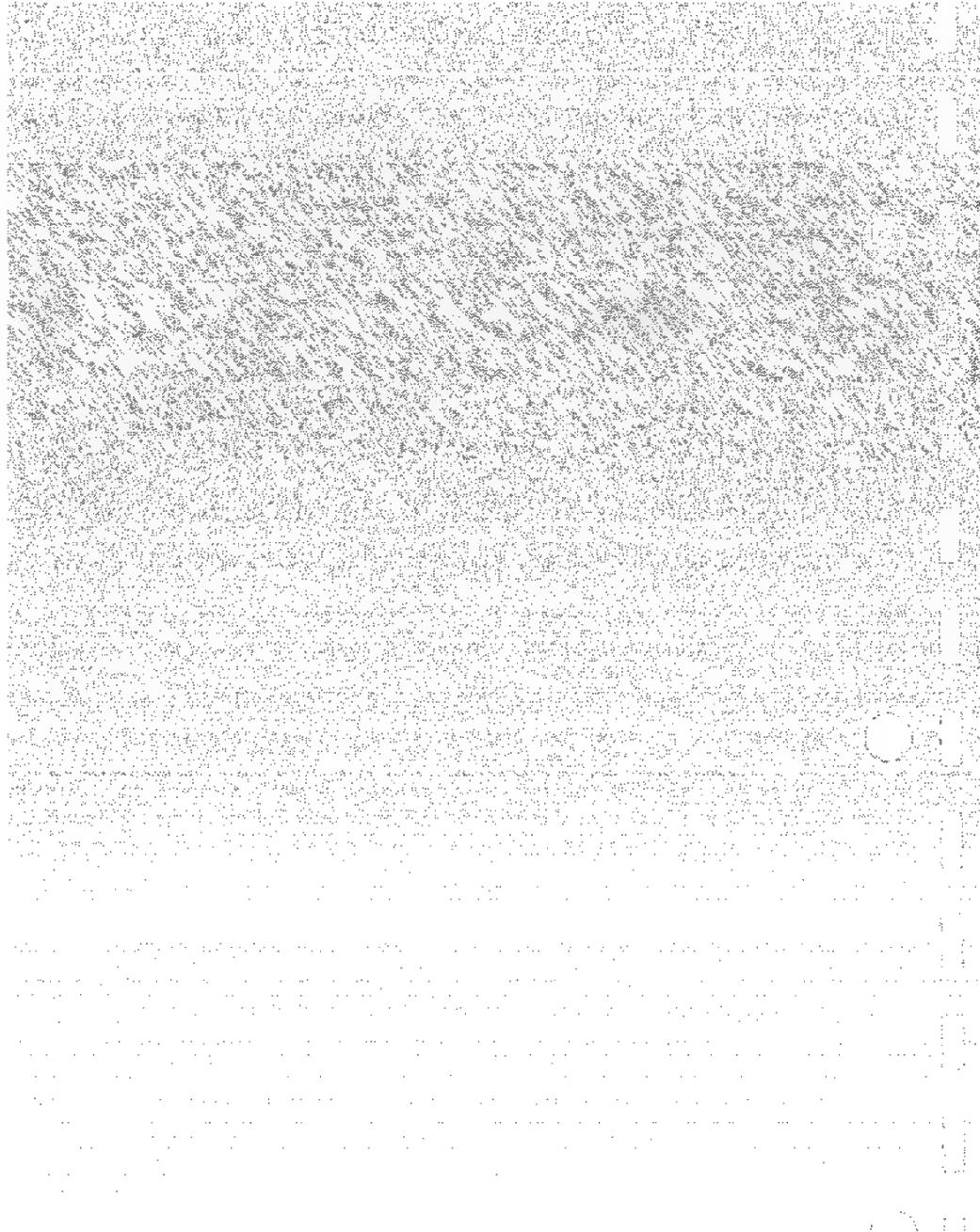
In order for the *INFUSO.R.* Pump to operate, a Smart Label must be attached to the pump face. If a label is not attached and the pump is turned "on", an internal fault will occur. Also, if the label is removed during pump use, an internal fault alarm will occur.

6. Two Infusion Rates Set

For Smart Labels that have High Infusion Rate and Low Infusion Rate switches, only one switch can be set. The other must remain in the zero position.

If two infusion rates are set, the pump will stop delivery and sound an audible alarm. To clear the alarm, return the undesired infusion rate setting to zero. The pump will then begin delivery at the set rate.





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IX. Flow Rates

The following equations may be used to determine the relationship among volumetric flow rate, body weight, and infusion rate in the *INFUSO.R.* Pump:

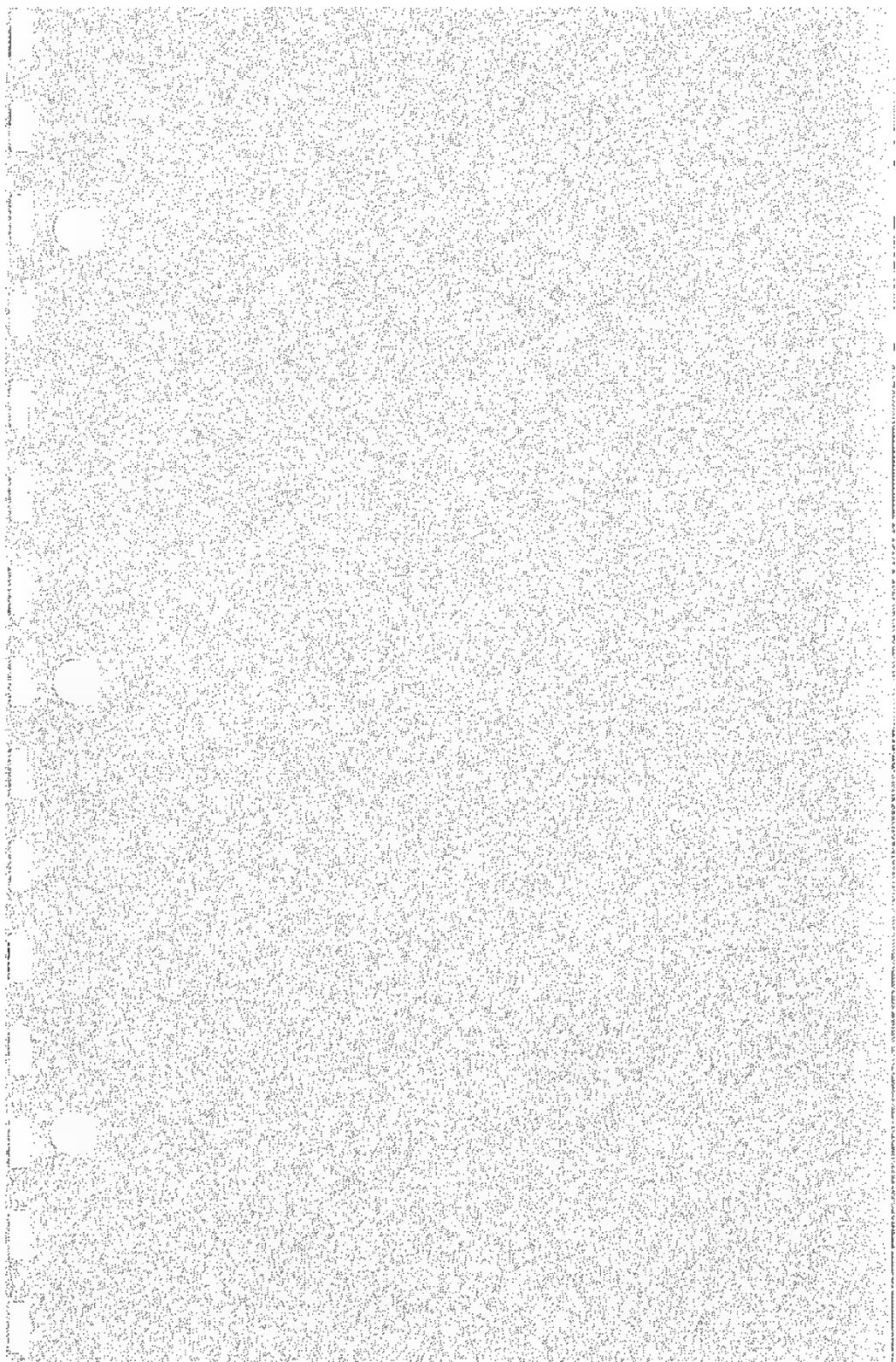
$$\text{Infusion flow (mL/min)} = \frac{\text{Infusion Rate (mcg/kg/min)} \times \text{Body Weight (kg)}}{\text{Drug Concentration (mcg/mL)}}$$

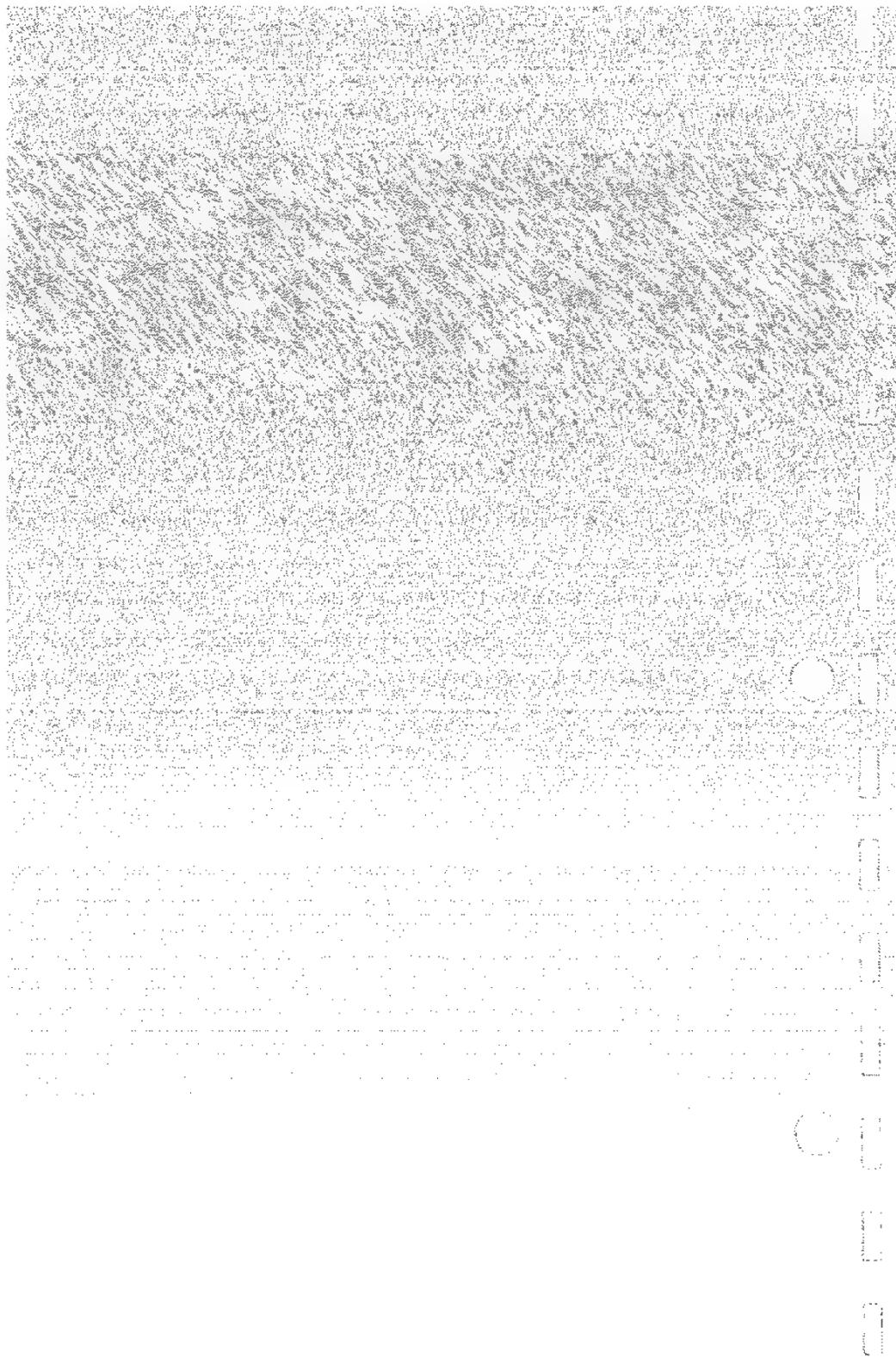
To determine total volume (in mL) for bolus settings, use the following:

$$\text{Total Bolus Volume (mL)} = \frac{\text{Bolus Dose (mcg/kg)} \times \text{Body Weight (Kg)}}{\text{Drug Concentration (mcg/mL)}}$$

To determine bolus duration (in minutes), use the following:

$$\text{Bolus duration (min)} = \frac{\text{Bolus dose (mcg/kg)}}{\text{Bolus Delivery Rate for Drug (mcg/kg/min)}}$$





X. ROUTINE MAINTENANCE

The *INFUSO.R.* pump is designed to provide many years of reliable service with only minor routine maintenance. A periodic functional inspection of the pump should be made at least every six months, or more frequently depending on use. The pump should also be cleaned and disinfected, as required, depending on frequency of use and hospital protocol.

Functional Inspection

To assure proper pump operation, the following items should be checked:

1. Pusher Block - Squeeze the release lever of the pusher block and check for free movement of the pusher over the complete travel range. Release the lever and check for engagement of the pusher block assembly.
2. Syringe Holder - Check the condition and holding ability of the syringe holder. Assure that 60 cc and 20 cc plastic syringes sit firmly in the holder and are retained by the barrel notch. Also, check that the anti-siphon latch of the pusher captures the syringe plunger to prevent siphoning.
3. End of Syringe Alarm - The End of syringe Alarm occurs when approximately 1 mL is remaining in the syringe. To check the alarm, place a syringe with the plunger located at approximately 3 mL in the pump. Initiate an infusion and check for:

- Flashing Infusion Light with the LCD incrementing in milliliters.
- Audible Alarm when End of Syringe occurs. The pumping operation should cease and the Attention light should flash. The display should flash EOS.
- Turn the pump OFF, then back to INFUSE. The alarm condition should resume when the pump is set to INFUSE.

4. Occlusion Alarm - The Occlusion Alarm occurs when the pusher encounters 8 ± 1 lbs. of force. To check the alarm, move the syringe holder downward while the pump is infusing (8 ± 1 lbs. force required). Check for:

- Audible Alarm and flashing Attention Light with pumping operation discontinued. The display should also flash OCC.

5. Input Switches - The front panel input switches should be checked for proper rotation and function. Check as follows:

- The three input switches should rotate through 12 discrete positions. Rotation directly from the highest to the lowest switch setting should not occur.
- Rotate the Function switch through 5 discrete positions. The two end positions are momentary and should return to the previous switch location upon release.

6. Syringe Manufacturer Selector Switch - The Syringe Selector switch should be checked to assure proper function. To check the switch, set the pump to any infusion rate setting and turn the Function switch to INFUSE. Change the Syringe Manufacturer Selector switch while the pump is infusing. An internal fault alarm should occur when the switch is changed.
7. Flow Rates and Delivery Volumes - The Bolus and Infusion Rates should be checked for delivery accuracy within $\pm 3\%$. For checking infusion rates, the following table provides the linear rate of the pusher for different Smart Labels. These rates span the dynamic operating range of the pump.

NOTE: Refer to the *INFUSO.R.* Service Manual (PN 5371160) for complete flow rate and delivery volume test procedures.

NOTE: When measuring these linear rates, the Syringe Manufacturer Selector switch MUST be in the B-D position.

INFUSO.R. Infusion Rates

Label #	Drug	Infusion Rate	Body Weight (Kg)	Linear Rate (inches/hr)
L01	Alfentanil	0.25 mcg/kg/min	30	0.0635 +/- 0.0019
	Amrinone	0.25 mcg/kg/min	30	0.0635 +/- 0.0019
	General mL/hr			
	Bolus	1.5 mL/hr	N/A	0.1058 +/- 0.0032
	Midazolam	0.5 mcg/kg/min	30	0.0635 +/- 0.0019
	Mivacurium	1 mcg/kg/min	30	0.0635 +/- 0.0019
	Mivacurium	Pediatric Dose 2.5 mcg/kg/min	12	0.0635 +/- 0.0019
	Low Concentration			
	Sufentanil	0.15 mcg/kg/hr	30	0.0635 +/- 0.0019
	Low Concentration			
	Fentanyl	0.15 mcg/kg/hr	30	0.0635 +/- 0.0019
	Succinylcholine	5 mcg/kg/min	30	0.0635 +/- 0.0019
L02	Propofol	25 mcg/kg/min	100	1.0569 +/- 0.0317
	Thiopental	10 mcg/kg/min	100	1.0569 +/- 0.0317
L03	Atracurium	8 mcg/kg/min	40	0.2632 +/- 0.0079
	Atracurium	Pediatric Dose 8 mcg/kg/min	8	0.2632 +/- 0.0079
L04	Vecuronium	1.2 mcg/kg/min	50	0.4929 +/- 0.0148
	Vecuronium	Pediatric Dose 1.2 mcg/kg/min	10	0.4929 +/- 0.0148
	Fentanyl	3.6 mcg/kg/hr	50	0.4929 +/- 0.0148
L05	Dobutamine	14 mcg/kg/min	60	0.7110 +/- 0.0213
L06	Dopamine	1.0 mcg/kg/min	70	0.0740 +/- 0.0022
L07	Isoproterenol	2.0 mcg/min	N/A	0.4230 +/- 0.0127
	Epinephrine	2.0 mcg/min	N/A	0.4230 +/- 0.0127
	Lidocaine	1.0 mg/min	N/A	0.4230 +/- 0.0127
	General mL	6 mL/hr	N/A	0.4230 +/- 0.0127
	Norepinephrine	4 mcg/min	N/A	0.4230 +/- 0.0127
	Phenylephrine	40 mcg/min	N/A	0.4230 +/- 0.0127
L08	Esmolol	100 mcg/kg/min	30	1.2683 +/- 0.0380
L09	Nitroglycerine	3 mcg/kg/min	90	1.1418 +/- 0.0343
	Nitroprusside	3 mcg/kg/min	90	1.1418 +/- 0.0343
L10	Sufentanil	0.8 mcg/kg/hr	50	0.1097 +/- 0.0033
	Sufentanil	Pediatric Dose 0.8 mcg/kg/hr	10	0.1097 +/- 0.0033

For checking Bolus distances, the following table provides the linear travel of the pusher block for different Smart Labels. These distances span the dynamic operating range of the pump.

NOTE: When measuring the Bolus travel, the Syringe Manufacturer Selector switch MUST be in the Monoject position.

***INFUSO.R.* Bolus Travel**

Label #	Drug	Bolus	Body Weight (Kg)	Displacement (inches)
L01	Alfentanil	15 mcg/kg	30	0.0635 +/- 0.0019
	Amrinone	150 mcg/kg	30	0.0635 +/- 0.0019
	General mL/hr			
	Bolus	1.5 mL/hr	N/A	0.1058 +/- 0.0032
	Midazolam	30 mcg/kg	30	0.0635 +/- 0.0019
	Mivacurium	60 mcg/kg	30	0.0635 +/- 0.0019
	Mivacurium			
	Pediatric Dose	150 mcg/kg	12	0.0635 +/- 0.0019
	Low Concentration			
	Sufentanil	0.15 mcg/kg	30	0.0635 +/- 0.0019
	Low Concentration			
	Fentanyl	0.15 mcg/kg	30	0.0635 +/- 0.0019
	Succinylcholine	300 mcg/kg	30	0.0635 +/- 0.0019
L02	Propofol	1000 mcg/kg	70	0.4932 +/- 0.0148
	Thiopental	400 mcg/kg	70	0.4932 +/- 0.0148
L03	Atracurium	200 mcg/kg	50	0.1215 +/- 0.0036
	Atracurium			
	Pediatric Dose	200 mcg/kg	10	0.1215 +/- 0.0036
L04	Vecuronium	100 mcg/kg	35	0.4248 +/- 0.0127
	Vecuronium			
	Pediatric Dose	100 mcg/kg	7	0.4248 +/- 0.0127
	Fentanyl	5 mcg/kg	35	0.4248 +/- 0.0127
L08	Esmolol	2000 mcg/kg	45	0.6346 +/- 0.0190
L10	Sufentanil	1.5 mcg/kg	40	0.1456 +/- 0.0044
	Sufentanil			
	Pediatric Dose	0.15 mcg/kg	8	0.1456 +/- 0.0044

8. Batteries - The pump batteries should be checked for a low battery condition. Check as follows:
 - Turn the Function switch to INFUSE. Check the Attention light and digital display.
 - If the Attention light flashes and the display shows LO BA then replace the pump batteries with four alkaline C-cells.

Cleaning and Disinfecting

The exterior surfaces of the pump and Smart Labels may be cleaned using a cloth dampened with water or a mild detergent, then wiped dry. A mild germicide may be used as a disinfectant. Baxter Healthcare Corporation recommends Vestal® LPH® or equivalent.

CAUTION: The *INFUSO.R* pump and Smart Labels are not waterproof and should not be immersed. Avoid getting liquids inside the pump or permanent damage may result. Do not use alcohol for cleaning. Sterilization via eto, steam, etc., should not be attempted.

Lubrication

The leadscrew should be lubricated at least every six months using Novagard Versilube® G-322L grease.

Vestal and LPH are registered trademarks of Vestal Laboratories, Inc., a subsidiary of Chemed Corp.

Versilube is a registered trademark of Novagard, Inc.

Using the nozzle applicator supplied with the grease, squeeze a small amount onto the entire length of the leadscrew. Do this by carefully inserting the nozzle straight into the case channel thereby spreading the rubber seal. Use care to avoid damage.

**CAUTION: Use only the recommended lubricant.
A substitute lubricant may cause
permanent damage.**

Technical Maintenance

Since specialized equipment is necessary to adjust the mechanisms and electronics inside the pump, it is recommended that a defective unit be returned to the factory for troubleshooting and repair. Should the pump appear to be malfunctioning, check for:

- Proper switch location
- Proper battery orientation (i.e., negative end first)
- Dead battery or batteries
- Proper Pusher location (i.e., not at end of syringe)
- Proper attachment of a Smart Label and that rear surface of Smart Label is clean and free of debris

Before returning the pump, contact your Baxter Healthcare sales representative for information on return authorization.

Storage

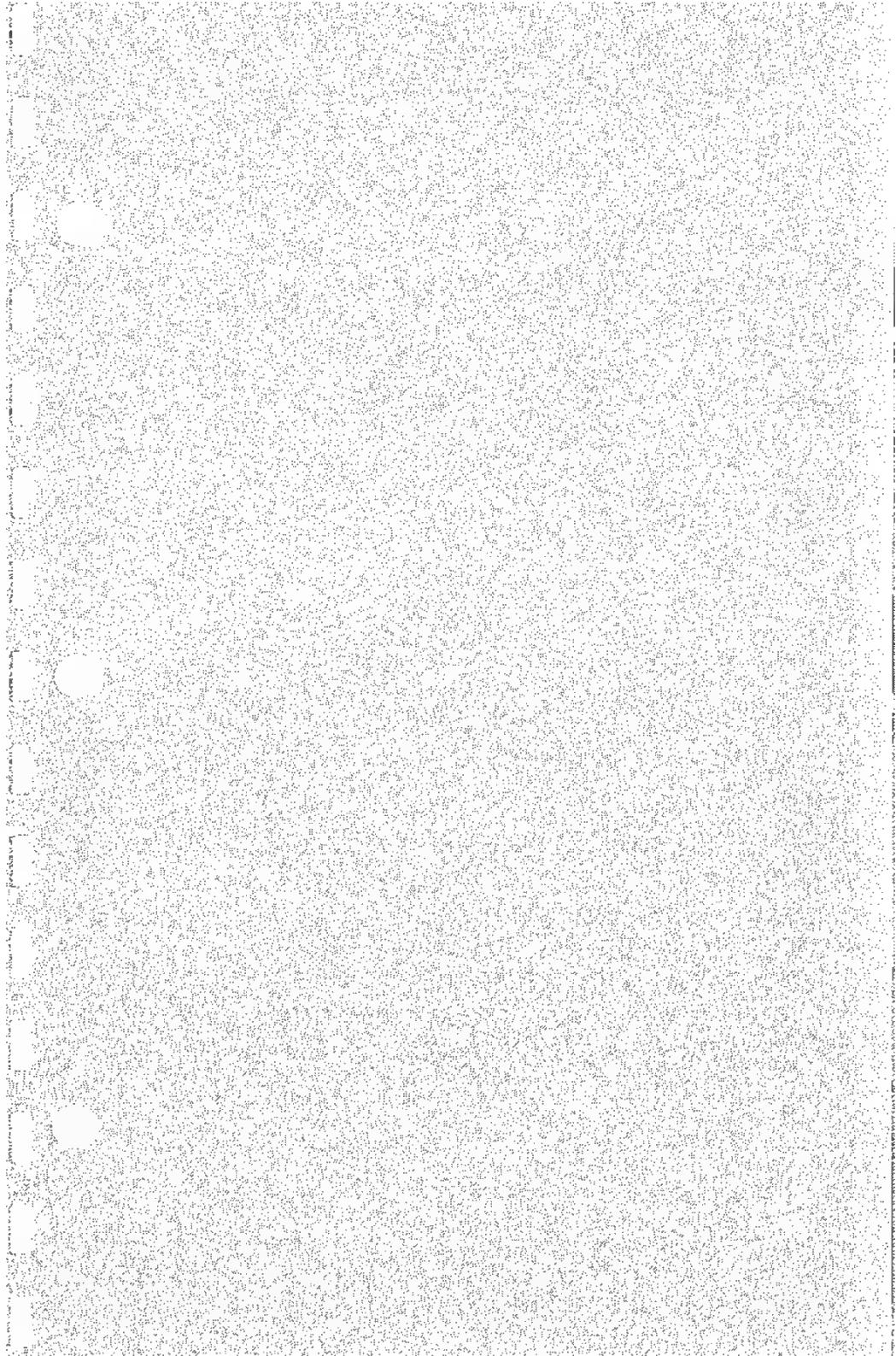
When the pump is placed in storage or is not in use for extended periods, the four C-cell batteries should be removed.

**BAXTER HEALTHCARE CORPORATION
LIMITED WARRANTY**

Baxter Healthcare Corporation warrants to the original purchaser that this Baxter Healthcare product will be free from defects in material and workmanship for a period of one (1) year from the date of its shipment from Baxter Healthcare to the original purchaser. If this product proves to be so defective, purchaser may return same to Baxter Healthcare for repair or replacement, at Baxter Healthcare's option. All returns must be authorized in advance in accordance with the Baxter Healthcare Returned Goods Policy found in its then current Price List. The liability of Baxter Healthcare under this limited product warranty does not extend to any abuse or misuse of this product or its repair by anyone other than an authorized Baxter Healthcare representative.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED INCLUDING ANY WARRANTY OF MERCHANTABILITY, SUITABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

THE LIABILITY AND REMEDY STATED IN THIS PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF BAXTER HEALTHCARE AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND BAXTER HEALTHCARE WILL NOT BE LIABLE TO PURCHASER FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGE ARISING OUT OF ITS HANDLING AND USE.



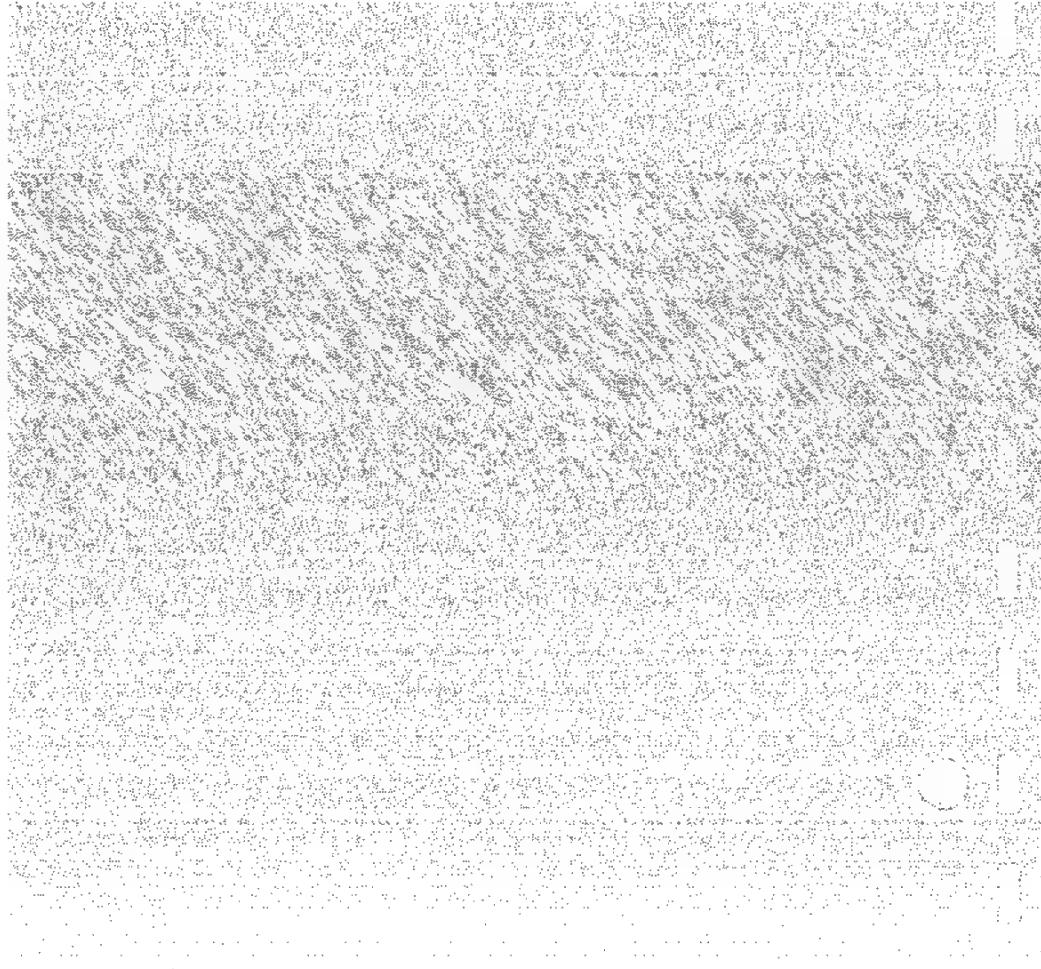


Figure 1. A high-contrast, black and white image showing a dense, granular texture. The texture is composed of numerous small, dark, irregular shapes that appear to be scattered across a lighter, textured background. The overall effect is similar to a heavily overexposed photograph or a close-up of a rough, granular surface like sand or gravel.

Figure 1 shows a high-contrast, black and white image of a granular surface. The image is dominated by a dense, granular texture, with numerous small, dark, irregular shapes scattered across a lighter, textured background. The overall effect is similar to a heavily overexposed photograph or a close-up of a rough, granular surface like sand or gravel. The texture is composed of many small, dark, irregular shapes that are scattered across a lighter, textured background. The overall effect is similar to a heavily overexposed photograph or a close-up of a rough, granular surface like sand or gravel.



XI. SPECIFICATIONS

Device Name	<i>INFUSO.R.</i> Pump	
Accuracy	Infusion:	Linear Rate $\pm 3\%$
	Bolus:	Linear Displacement $\pm 3\%$
Battery Life	Typical Use:	150 hours
	At Low Battery and Typical Use:	4 hours
Batteries	Four "C" -size Alkaline Cells (NEDA 14A)	
Operating Voltage	5 - 7 Volts	
Operating Current	20mA	
Low Battery Voltage	5.0 Volts Approximate	
Flow Rates	0 to 600 mL/hr, depending on the Smart Label	
Flow Profile	Bolus:	Continuous
	Infusion:	Pulsed intermittently
Occlusion Force	8 ± 1 lbs. (pressure)	
Maximum Occlusion Pressure	11 psi w/ 60 cc syringe 20 psi w/ 20 cc syringe	
Occlusion Detection Time*	120 seconds at 36 mL/hr (Inversely related to flow rate)	
Volume Stored on Occlusion*	1.1 mL Approximate	

* Using a Microbore Anesthesia Set and a 60 cc syringe.

**Back Pressure Effect
on Accuracy** **None to Occlusion Pressure**

Size **9.2 x 4.5 x 2.0 inches
(238 x 113 x 50mm)**

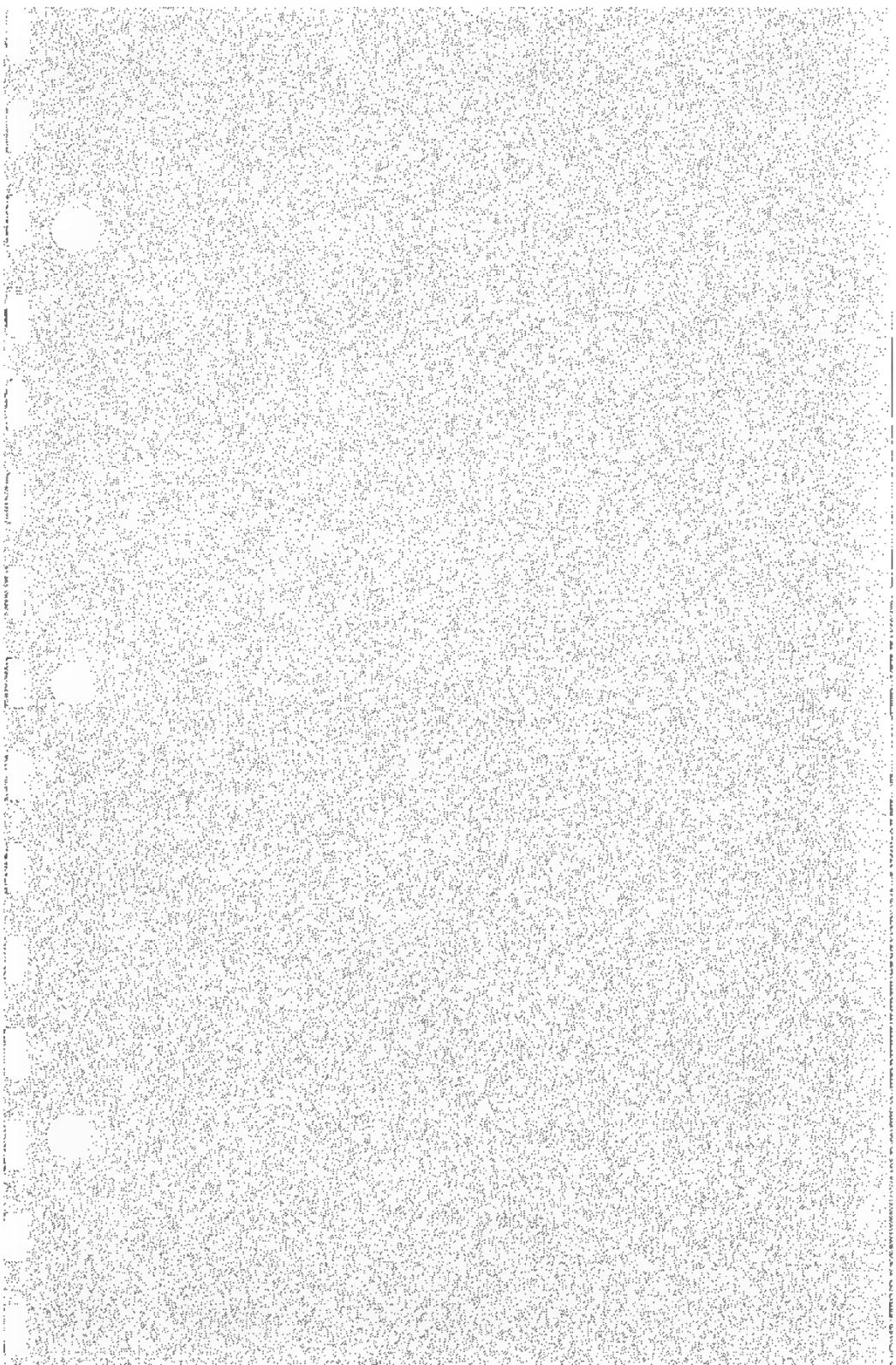
Weight **2 lbs.(1Kg) with Batteries**

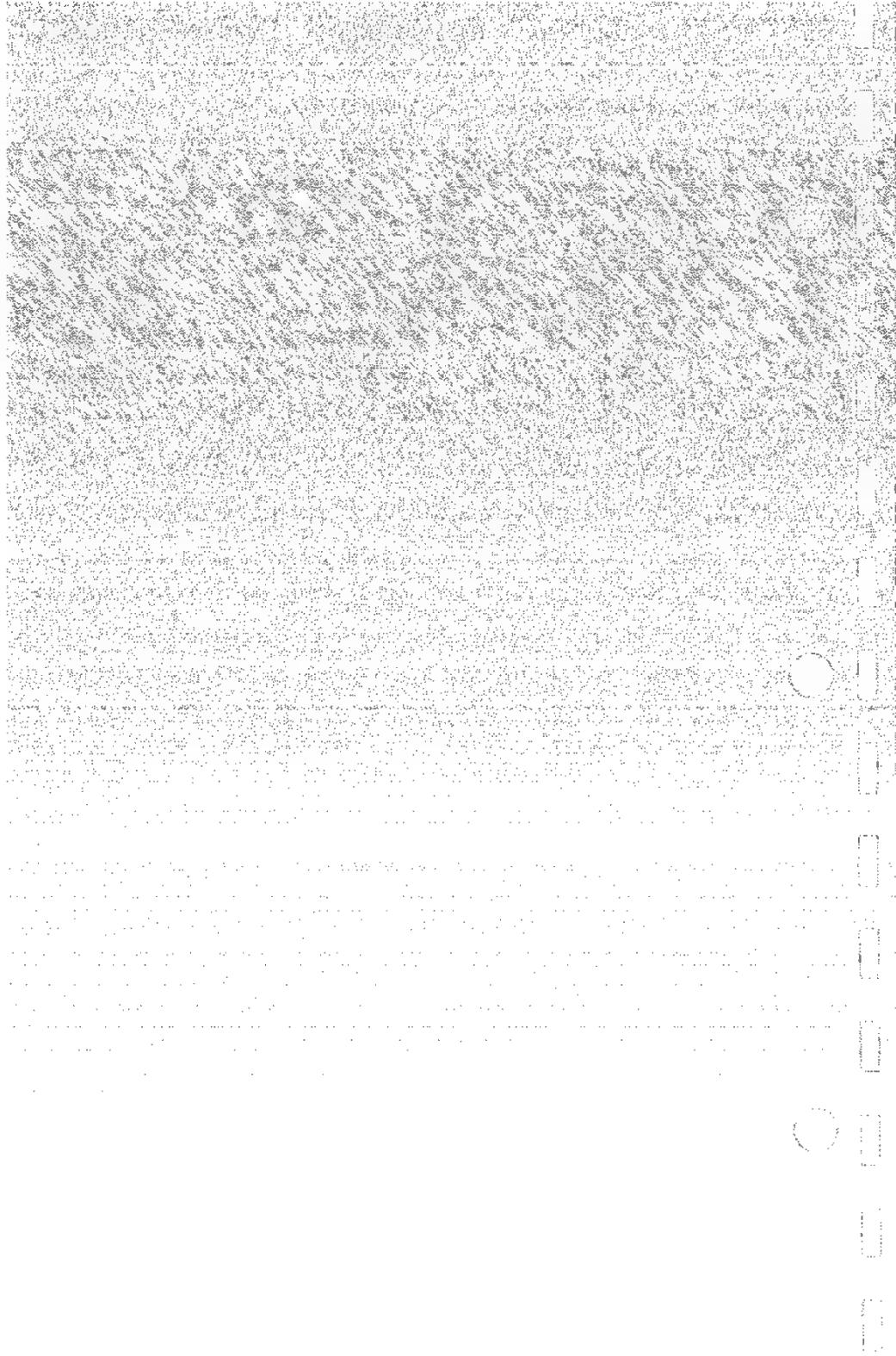
Syringes **Monoject® or B-D® 60 cc
Monoject® or B-D® 20 cc**

 **Drip proof equipment:** prevents entry of falling liquids.
Product is not watertight, do not immerse in liquid or expose to possible splash or sprayed liquids.



Type BF Equipment: internal power source (batteries) with an isolated (floating) applied part.





XII. THIS INFUSION PUMP IS SUBJECT TO TRACKING

Pursuant to Title 21 of the U.S. Code of Federal Regulations, Part 821, "Medical Device Tracking Requirements", customers within the United States have certain obligations in furthering the tracking of Infusion Pumps.

You should verify equipment serial numbers against those listed on the packing slip. If correct, indicate this on the packing slip by signing and dating the slip. Should any of the information be incorrect, please contact us at 1-800-THE-PUMP. To facilitate future communications, in addition to your signature, please print your name, title and telephone number on the packing slip. Return a copy of the packing slip to Baxter Healthcare, IV Systems Division.

Any format of verification that provides the required level of information is acceptable.

Infusion pump tracking within the hospital (or other types of user facilities) is not required. Please refer to page 43453 of the rule for further information. However, should you allocate any of your facility's infusion pumps for home patient use, you have additional tracking requirements. You must maintain a current patient and physician registry, by serial number, in a format that can be provided to the manufacturer within 5 working days. Should you sell a pump to a patient, you must promptly provide us with the patient and physician information.

The final rule on device tracking clarifies the responsibility of hospitals and other user facilities within the United States. The following Fact Sheet summarize these requirements. We would recommend that you develop written procedures that outline your operation's device tracking compliance plan.

INFUSION PUMP MEDICAL DEVICE TRACKING FACT SHEET

- 1. Scope:** Per 21 CFR Part 821, infusion pumps have been categorized by the FDA as devices which must be tracked. If used within a device user facility (i.e. hospital, nursing home), tracking *to the user facility* is required. If the infusion pump is used outside a device user facility, the distributor who provides the device to a patient must keep records of the infusion pump's location and subsequently report this information to the manufacturer.

2. Effective Date: August 29, 1993

3. Definitions

User Facility	hospital, nursing home, ambulatory surgical facility, or diagnostic facility
Distributor	any entity who furthers the distribution of a device from the original place of manufacture to the person who makes delivery or sale to the ultimate user, i.e., the final or multiple distributor, but who does not repack or otherwise change the container, wrapper or labeling of the device or device package
Final Distributor	any entity who distributes a tracked device intended for use by a SINGLE patient over the useful life of the device.
Multiple Distributor	any entity that distributes a tracked device intended for use by MORE THAN ONE patient over the useful life of the device

- 4. Distributors (consignees) are required to REPORT TO THE MANUFACTURER the purchase, receipt in trade, return after sale, loss, destruction or retirement of any tracked medical device.**

Required Information:

- Name and address of the distributor (consignee)
- Model and serial or lot number of the device
- Date the device was received
- From whom the device was received
- Date of permanent distribution, i.e., loss, destruction, retirement

5. Upon DISTRIBUTION OF A TRACKED DEVICE FOR USE IN OR BY THE HOME PATIENT, the following record must be maintained by the distributor (final or multiple distributor who places the device in the home environment) for the useful life of the tracked device. Note useful life is defined as the time a device is in use or in distribution channels for use.

Required Information:

- Model and serial or lot number of the device
- Patient's name, address and telephone
- Date the device was provided to the patient
- Prescribing physician's name, address and telephone
- Attending physician's name, address and telephone

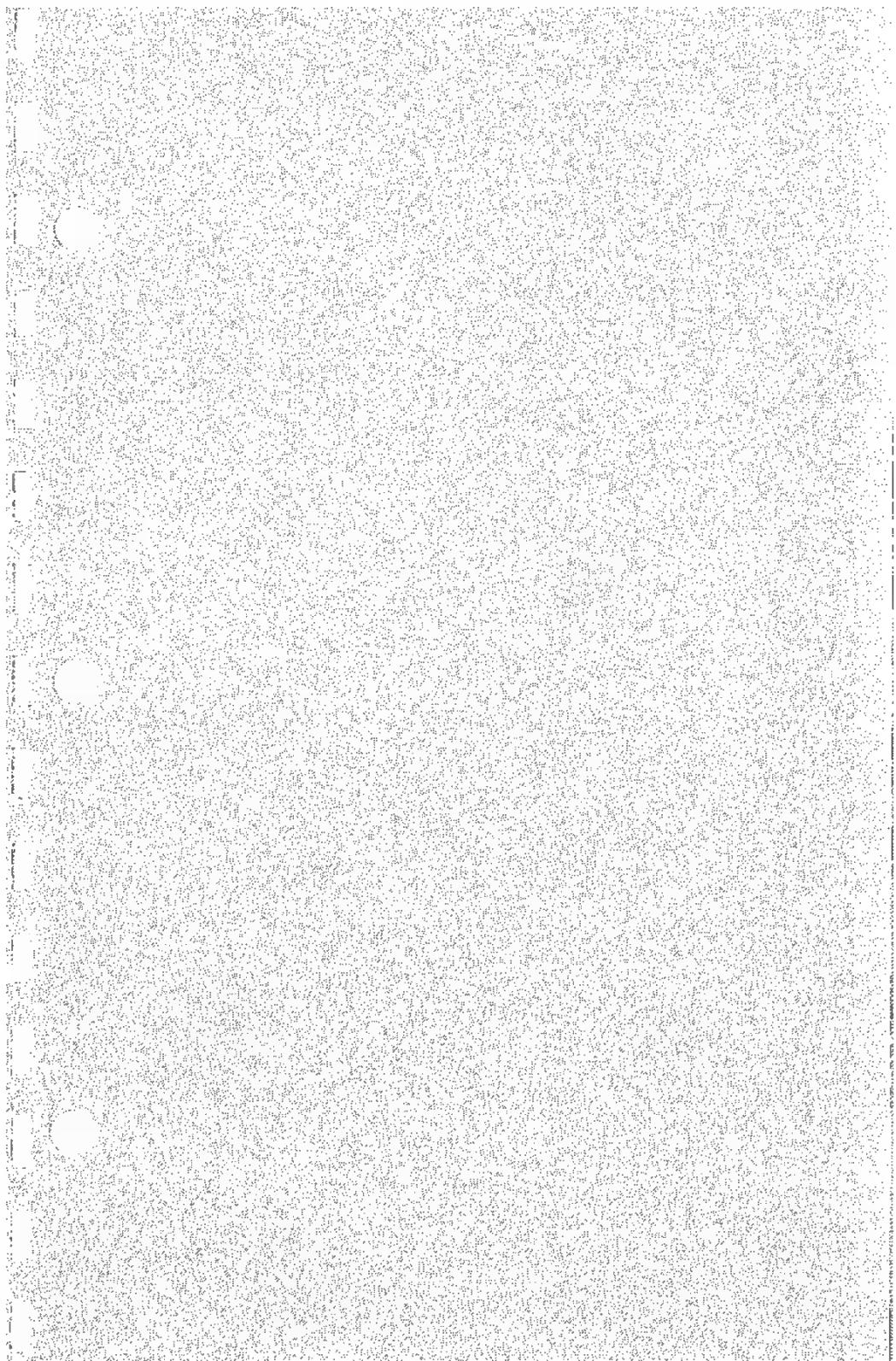
6. Reporting Requirements

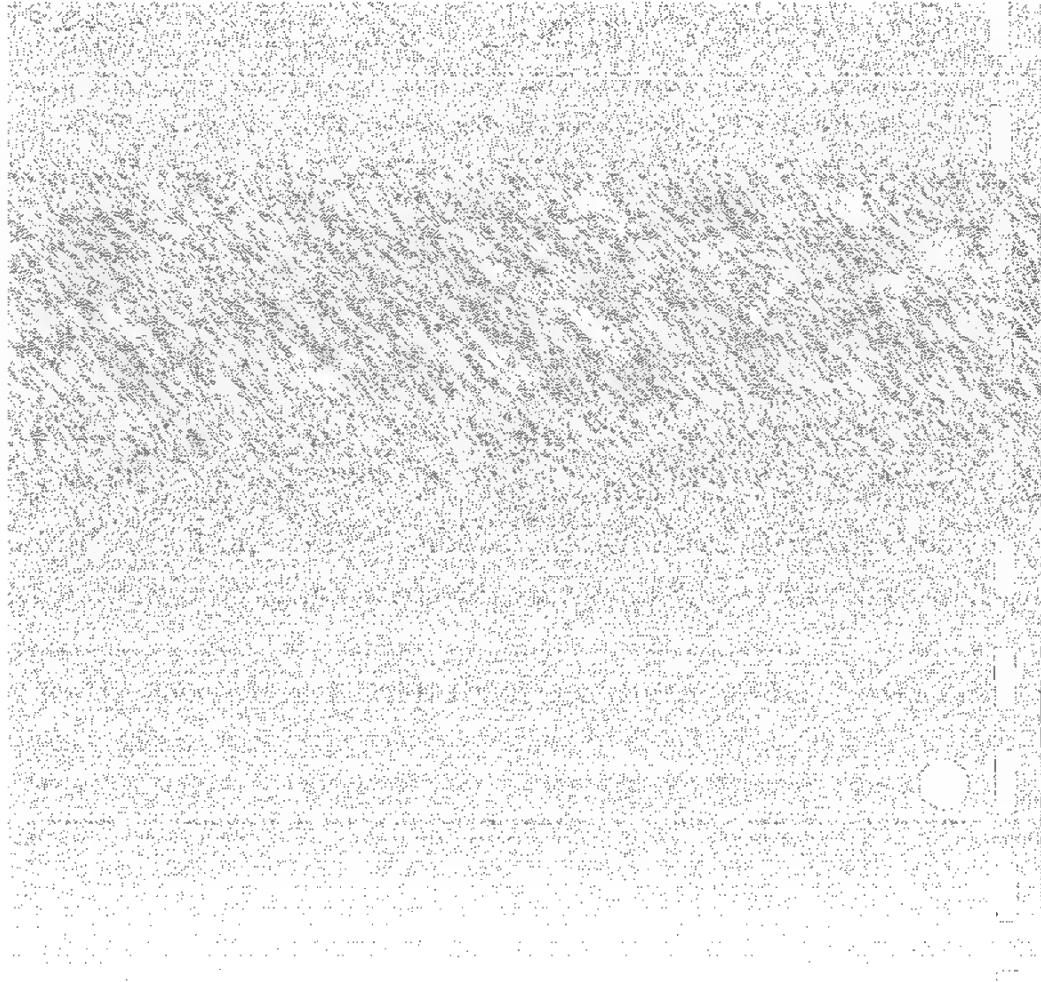
The following information must be reported:

DATA	TIME FRAME ALLOWED TO OBTAIN INFORMATION
Manufacturer's distribution/inventory records	3 working days
Final distributor's patient and physician records	Reported to the manufacturer promptly following distribution to the patient
Multiple distributor's patient and physician records	Upon request, reported to the manufacturer within 5 working days
Manufacturer's patient records	10 working days (for multiple patient use devices such as Infusion Pumps) i.e. multiple distributor's registries

7. Audit Requirements

In addition, a statistically relevant sample of the manufacturer's consignees must be audited every 6 months for the first three years, then annually, to ensure compliance with tracking regulations. Customers who are not complying with this regulation must be reported to the FDA.





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XIII - ATTACHMENT

"Representative Smart Label Instruction Sheet" - Provided for reference purposes only. Always refer to the Instruction Sheet provided with each Smart Label at the time of use.

Smart™ Label for Use with the InfusO.R.™ Pump

A. General Description

The Smart™ Label is designed exclusively for use with the InfusO.R.™ Pump. When attached to the InfusO.R. Pump as described in the User's Manual, the pump's microprocessor will decode magnetic sensors in the Smart Label to determine delivery rates. The InfusO.R. Pump will then deliver the drug in the syringe at the indicated infusion rates. Each label has a label number, for identification purposes, which is located on the upper right section of the Smart Label.

B. Indications for Use

The InfusO.R. Pump and its Smart Labels are intended for controlled rate delivery of small volume parenteral fluids. Each Smart Label is intended for use with the drug indicated on the label at the specified concentration for delivery. The drug is delivered from either a 20 cc or 60 cc syringe which is also indicated on the Smart Label.

C. Warnings

Before using any Smart Label or the InfusO.R. Pump, refer to the full prescribing information supplied by the drug manufacturer.

D. Precautions

Refer to the InfusO.R. Pump User's Manual for complete operating instructions and additional precautions.

USE OF TUBING SETS OTHER THAN BAXTER TUBING SETS MAY RESULT IN NUISANCE ALARMS OR REQUIRE EXCESS PRIMING VOLUME.

FLOW RATE OF PRIMARY IV SOLUTION MUST BE FAST ENOUGH TO PROVIDE TIMELY DELIVERY OF DRUGS INFUSED VIA THE PUMP.

THE FOLLOWING STEPS WILL HELP AVOID INADVERTENT BOLUS EFFECTS WHEN USING THE INFUSO.R. PUMP:

- Use only appropriate tubing sets to minimize priming volume and tubing set compliance.
- Use a high rate running primary IV.
- Use primary IV sets with backcheck valves to prevent drug back-up into the primary line.
- Attach any extension set to the primary access site nearest the patient to minimize drug transit time and resident volume in the primary IV.

The pump delivery rates are shown on each Smart Label. For labels that provide a bolus delivery function and have Body Weight settings between 30 and 100 kg, the bolus delivery rate is determined by multiplying the drug concentration by the factor listed in the table below.

Label Number	Multiply Concentration by	Notes
1	0.1	
2	0.1	
3	0.04	
4	0.05	
8	0.05	To determine each Smart Label's Bolus Delivery Rate in $\mu\text{g}/\text{kg}/\text{min}$
10	0.03	

For the Pediatric Smart Labels that provide a bolus delivery function, the bolus delivery rate is determined by multiplying the drug concentration by the factor listed in the table below.

Label Number	Multiply Concentration by	Notes
1	0.25	
2	0.20	
3	0.20	
4	0.25	To determine each Smart Label's Bolus Delivery Rate in $\mu\text{g}/\text{kg}/\text{min}$
10	0.15	

WARNING: THE DRUG CONCENTRATION AND/OR BODY WEIGHT SETTINGS FOR PEDIATRIC SMART LABELS ARE REDUCED COMPARED TO THE STANDARD CONCENTRATION AND BODY WEIGHT SETTINGS FOR THE CORRESPONDING ADULT SMART LABEL. FAILURE TO DILUTE THE DRUG AS INDICATED ON THE BACK OF EACH PEDIATRIC SMART LABEL MAY RESULT IN OVERDOSAGE.

E. Instructions for Use

The Smart Label shows the label number in the top right corner of the label. When the pump is first turned on with the Smart Label in place, the pump's liquid crystal display will show the label number. The drug concentration for use in the pump is in the color coded section of the label. Directly below this section, the syringe size for use with each drug is listed. Precautions for use of the pump are given on the back of the Smart Label.

When using the InfusO.R. Pump with the Smart Label:

1. Prepare the appropriate sized Monoject or B-D syringe with the required volume of drug.
2. Verify that the concentration of drug in the syringe is as required and label the syringe with the drug name and concentration.
3. Connect an appropriate Baxter tubing set to the syringe and manually purge the tubing set of air.
4. Place the properly prepared syringe in the pump following the Instructions for Use section in the InfusO.R. Pump User's Manual.

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THIS ISSUE DATE IS INCLUDED FOR THE USER'S INFORMATION. IN THE EVENT THAT TWO YEARS HAVE ELAPSED BETWEEN THIS DATE AND PRODUCT USE, CONTACT BAXTER AT (800)933-0303 TO SEE IF ADDITIONAL PRODUCT INFORMATION IS AVAILABLE.

CAUTION: Federal (USA) law restricts this device to sale by or on order of a physician.

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